Limits to the validity of contracts on human tissue in Italy, England and the EU

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A comparative analysis

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A comparative analysis

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Bogotá, 20 April 2020

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List of Abbreviations

C.C.	*Codice Civile Italiano*
C.P.	*Codice Penale Italiano*
Cass.	*Corte di Cassazione*
CFREU	Charter of Fundamental Rights of the European Union
CJEU	Court of Justice of the European Union
Corte Cost.	*Corte Costituzionale*
Cost.	*Costituzione della Repubblica Italiana*
D.P.C.	Data Protection Code
DPA 1998	Data Protection Act 1998
DPA 2018	Data Protection Act 2018
ECHR	European Convention of Human Rights
ECtHR	European Court of Human Rights
EU	European Union
GDPR	General Data Protection Regulation
HRA	Human Rights Act 1998
HTA	Human Tissue Authority
HTAct	Human Tissue Act 2004
UDHR	Universal Declaration of Human Rights
WHO	World Health Organization

Part 1

Introduction

Chapter 1

Background, scope and research questions, delimitation and terminology, methodology and structure

PART 1 INTRODUCTION

CHAPTER 1 Background, scope and research questions, delimitation and terminology, methodology and structure

1.1 Background

The development of new technologies in genetic research and the increasing understanding of the human genome has led, in the last decades, to an increase in the use of human tissue in the fields of research, diagnosis and medical treatment. In fact, the potential commercial use of genetic information and the findings of research on human tissue have awakened a growing interest of private companies on this kind of bodily materials. The exchange of human tissue that up until the 1970's happened without the need of any formal agreements is now privately regulated by contracts.[1] The use of these contracts runs parallel to an unprecedented growth of the global biotechnology market: by 2017 the market was estimated to be worth 414.5 USD and, by 2025, it is expected to reach a value of 727.1 billion USD.[2]

The existence and growth of this market is, paradoxically, supported by a large national, supranational and international legislative consensus on the prohibition of making the human body and its parts, as such, a source of financial gain.[3] At the European level, just to give an example, Article 3.2.c of the Charter of Fundamental Rights of the European Union,[4] –mirroring Article 21 of the Oviedo Convention[5]– prescribes that "(i)n the fields of medicine and biology, the

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[1] Rodriguez, 2005, p. 489; Streitz and Bennett, 2003, p. 10.

[2] Data obtained from the following reports: 1) Global Biotechnology Market by Application (Biopharmacy, Bioservices, Bioagri, Bioindustrial), by Technology (Fermentation, Tissue Regeneration, PCR, Nanobiotechnology, DNA Sequencing & Others) - Industry Analysis, Size, Share, Growth, Trends and Forecast, 2010 - 2017 Report at <http://www.transparencymarketresearch.com/biotechnology-market.html> last consulted, 2 November 2019; 2) Grand View Research, Inc. Biotechnology market <https://www.grandviewresearch.com/press-release/global-biotechnology-market> last consulted, 2 November 2019.

[3] See Chapter 9 on the prohibition of financial gain.

[4] Charter of Fundamental Rights of the European Union (2012/C 326/02) Published in the Official Journal of the European Union C 326/391 the 26th of October 2012. The Charter of Fundamental Rights of the European Union was proclaimed the 7th of December 2000, and entered into force the 1st of December 2009 with the Treaty of Lisbon.

[5] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine Oviedo*, 4.IV.1997, CETS 164 (thereafter: 'Oviedo Convention on Human Rights and Biomedicine 1997'). For full text see: <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm> last accessed 2 November 2019.

For an overview of the literature on the Oviedo convention see for example: Lawson, 2010; Andorno, 2009; McCrudden, 2008; Den Exter, 2010; Beyleveld and Brownsword, 1998.

following must be respected in particular: (…) –the prohibition on making the human body and its parts as such a source of financial gain."

Precisely because of the aforementioned prohibition on making the human body and its parts, as such, a source of financial gain, the market on human tissue is divided between downstream and upstream players. The upstream players, represented by the initial tissue 'donors', are, at first, not allowed to obtain direct economic befits arising from the transfer of their tissue.[6] The downstream players, which include hospital, brokers, pharmaceutical companies and universities, can obtain direct economic benefits and, in some cases, are able to appropriate and restrict the access to genetic resources (and their products) via patenting technics.[7]

Downstream players (with academic or commercial purposes) looking for human tissue to develop their studies have two possible ways of obtaining them. On the one hand, they can obtain them from the original source of the materials, i.e. a person (alive or dead). On the other hand, they can obtain them from other institutions (hospitals, universities, etc.) by making use of contracts denominated Material Transfer Agreements (MTAs).[8] A Material Transfer Agreement has been defined as "a contract that governs the transfer of tangible research materials between two organizations, a provider and a recipient, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Biological materials such as specimens, reagents, cell lines, plasmids and vectors, are the most frequently transferred materials, but MTAs may also be used for other types of materials, such as chemical compounds and even types of software."[9]

However, contracting via MTAs is only the second step of a chain that starts when the upstream players, i.e. the donors transfer for the first time their tissue to one of the downstream players.

In both steps of the chain the use of human tissue for research raises an innumerable amount of other ethical and legal issues e.g. the protection of human dignity, privacy, autonomy, health and other fundamental rights of the

[6] I use the term donor to refer to the first transferor of the tissue, independently of whether or not the title of the transfer is a donation contract.

[7] On gene patents see, for example, Koepsell, 2009.

[8] For the notion of material transfer agreement see Rodriguez, 2005.

[9] International Society for Biological and Environmental Repositories (ISBER), *Best Practices for repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research,* 2001 (Third Edition) p. 88. <http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/Files/ISBER_Best_Practices_3rd_Edi.pdf?hhSearchTerms=%22contract+and+governs+and+transfer+and+tangible+and+research+and+materials+and+between+and+two+and+organizations%2c+and+pro%22> last accessed 2 November 2019. See also the Guiding Notes for Academic Staff on Material Transfer Agreements by the Imperial College of London <https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/research-office/public/MTA-Guidance-Notes-Academic-Staff-[pdf].pdf> last accessed 2 November 2019.

first transferor of the tissue; the protection of other rights and interests of all stakeholders involved and; the requirements for the validity of consent for the transfer of tissue. Which legal mechanisms can be implemented for the protection of the rights and interests of the person from whom the tissue has been extracted and other stakeholders?

Several models have been proposed for the protection of the rights of the original source of the tissue and for the circulation and use of this material for research: a. the informed consent model, b. the proprietary model and, c. the contractual model. According to the first model, the legal basis for the extraction, use and circulation of tissue for research is the informed consent of the person from whom the tissue has originated. According to the second model, such basis is the existence of property rights on the human body and its parts, and not necessarily the consent of the original source of the material. This book explores the third possibility. According to the contractual model, the conclusion of contracts could protect better than any other mechanism the rights and interests of the parties involved in the circulation of human tissue for research.[10]

Although there have been several proposals to implement the contractual model for the use and circulation of human tissue, there is not a systematic comparative study that analyses the various possible legal limits to the conclusion of contracts on human tissue.[11]

1.2 Scope and research question

Against the previous background, this book investigates the following research question:

- What are the limits to the validity of contracts on human tissue for research purposes in the Italian and English legal system?

In order to establish such limits, this study focuses on the following possible cases of contractual relations for the transfer and use of human tissue: **a)** Gratuitous contracts between the first transferor and the first recipient; **b)** Non-gratuitous contracts between the first transferor and the first recipient; **c)** Contracts between the first and subsequent recipients. The reader will find in the comparative part of this book a systematic answer to the research question in relation to the aforementioned investigated cases.

Although the research question investigated in this book can be framed within the much broader debate about the limits to the acts of disposition of the human body, its scope is exclusively limited to the validity of contracts on human tissue

[10] Noiville, 2016, p. 145.

[11] On the contractual model see, among others, Bellivier & Noiville, 2004; Dick, 2002; Weck, 2005, p. 1057.

for the purposes of research. The reason for this restriction is that the problems that arise from the use of human tissue for research are different from the ones that other purposes, or other parts of the human body (e.g. human organs) give rise to.

Generally speaking, human tissue has a double "nature". On the one hand, human tissue is a separated part from the human body. On the other hand, human tissue is a source of personal (e.g. health and genetic) data. For this reason, the moral and legal problems derived from the use of human tissue for research have to do with, at least, one of the two "natures" of human tissue. Some of these problems include, but are not limited to, the following questions: a) is the consent of the donor necessary for the extraction, use and contractual transfer of human tissue and the data associated to it? b) If so, what is the scope of such consent? c) Which information should be provided to the donor to consider the consent valid? d) Can the first recipient of the tissue transfer it to other parties without the consent of the first transferor? e) What are the most appropriate legal and technical safeguards that should be put in place to protect the personal data of the donor? f) Could the contractual transfer and use of human tissue threaten the human dignity and other fundamental rights of the donor? g) Can human tissue be the object of non-gratuitous contracts? h) Should non-gratuitous contracts on human tissue be prohibited on the grounds of an alleged exploitation and coercion of the donor? i) In contracting on human tissue, what is the interplay between individual autonomy and paternalism?

This book intends to give an answer to these questions in terms of limits to the validity of contracts on human tissue.

1.3 Delimitation and terminology

1.3.1 International law, supranational law and national legal systems

This study focuses on the interplay between international and supranational law and the national legal systems of Italy and England.[12] In this regard, I identified the possible legal documents that may impact, depending on the effect on each national legal system, the determination of the limits to the validity of contracts on human tissue. Broadly speaking, two types of legal sources are addressed in this book. On the one hand, international and supranational documents on fundamental and human rights, e.g. ECHR,[13] the Oviedo Convention and the

[12] In this book the references to the English legal system or to English law are to be understood as the legal sysem and law of England & Wales.

[13] Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, Europ. T.S. No. 5; 213 U.N.T.S. 221.

CFREU. On the other hand, international and supranational documents on data protection, e.g. the General Data Protection Regulation.[14]

The study of this book was limited to countries belonging to the EU. The reason for this choice is that it allowed analysing the differences in the effect of supranational legal sources on the limits to the validity of contracts on human tissue in different national legal systems. Within the EU, the case studies were further restricted to Italy and England. The choice of these two national legal systems answers to different rationales. Firstly, Italy is the only European country that originally included in the national civil code a provision (Article 5 C.C) regarding the acts of disposition of human body.[15] This particularity nurtured a long and fertile scholarly literature on the legal status of the human body and its parts. Secondly, unlike many other European countries, England has special legislation regarding the use of human tissue, i.e. the Human Tissue Act 2004.[16] These special conditions in each of the national countries investigated allowed for an interesting comparative analysis of the limits to the validity of contracts on human tissue. While in the Italian case, a relatively old (1942) civil code provision set the initial parameters for the determination of such limits, in the English case, a relatively new instrument of statutory law, comprehensively regulates the use of human tissue. Thirdly, both countries were chosen because they belong to different legal families and traditions. This fact enabled the analysis of the question of whether or not the differences in legal technique in both national legal systems could result in different answers to moral and legal questions, i.e. the question of the validity of contracts on human tissue. An initial intuition, later on confirmed during the research period of this study, suggested that the absence of a written constitution in England and the differences in the legal treatment of contracts between the two legal systems could constitute relevant factors for the determination of the limits to the contracts analysed in this book.

1.3.2 Terminology

[14] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, hereafter: GDPR).

[15] The Italian Civil Code of 1942 was the only one, from the old European civil codes, that incorporated a provision regarding the acts of disposition of the human body and its parts. However, other legal systems, following modern developments, incorporated later on provision on the human body. That is the case of the French Civil Code. This Code, after a reform by the law "*n°94-653 du 29 juillet 1994 - art. 3 JORF 30 juillet 1994*" incorporated Article 16.1 which prescribes that "*Chacun a droit au respect de son corps. Le corps humain est inviolable. Le corps humain, ses éléments et ses produits ne peuvent faire l'objet d'un droit patrimonial.*"

[16] Human Tissue Act 2004, <http://www.legislation.gov.uk/ukpga/2004/30/contents> accessed 2 November 2019.

-Human tissue and human biological samples

This book prefers the term 'human tissue' over other similar terms for two reasons. Firstly, because the term human tissue gives the reader an immediate clearer idea of the subject matter of the book than other terms like 'human biological material' or 'human biological samples'. Secondly, because human tissue is the term used by the English legal system in the Human Tissue Act 2004. Unless otherwise specified, in this work the term human tissue is to be understood as bodily samples, separated from the human body, that contain the genetic information of an individual.[17]

However, in the chapters related to data protection law I have preferred to use the term 'human biological samples'. These chapters use the term 'human biological samples'[18] instead of the term 'human tissue' because it is a terminology commonly used by both data protection law scholars and scholars from other disciplines than law dealing with the research on the human body and its parts.[19] Furthermore, the same terminology is used by GDPR. In the data protection chapters, the term 'human biological samples' refers to tissue of human origin used for research purposes.[20]

Three further clarifications are necessary in this regard. Firstly, in this book the terms human tissue or human biological sample do not include gametes (sperm and ova), embryos or human organs. Although related, these particular types of bodily materials give raise to different problems in the fields of bioethics and law. It would be far outside the scope of this book to include them in the analysis. Secondly, this book focuses on contracts on human tissue for research purposes. For similar considerations, the use of human tissue for transplant or other therapeutic purposes falls outside the aim of this research. Thirdly, in this book the terms 'donor', 'first transferor of the tissue' and 'original source of the tissue' are used interchangeably and independently of whether or not the title of the transfer is a donation contract.

-Horizontal effect of fundamental rights

The definitions of horizontal effect, direct horizontal effect and indirect horizontal effect vary from one scholar to another. This book shares an understanding of these three concepts that seems to be widespread in the European private law literature. Accordingly, the horizontal effect of a fundamental right or constitutional principle is the reference made to this right or principle in order to shape the rights and duties of the parties of a private

[17] In this definition I follow the one provided by Jiménez, 2003.
[18] The italian term for human biological samples is '*campioni biologici umani*'. Cfr. Novelli & Pietrangelli, 2011, p. 1028.
[19] Wendler & Emanuel, 2002; Wendler, 2006; Cambon-Thomsen 2004.
[20] Human biological samples can also be used for diagnostic and therapeutic purposes. Cfr. Novelli and Pietrangelli, 2011, p. 1028.

relationship. A common way to distinguish between direct and indirect horizontal effect is to identify the term 'direct horizontal effect' with the foundation of a private law remedy directly on a fundamental right or constitutional principle, and 'indirect horizontal effect' with the interpretation of a private law rule in the light of a fundamental right or constitutional principle. Other views, especially in English scholarly works, seem to use the term 'horizontal effect' in a way that resembles the above-mentioned understanding of 'direct horizontal effect'.[21]

-*Final terminology remarks*

The use of the pronouns 'she' or 'her' is meant to include the pronouns 'he' or 'his'.
Unless otherwise specified, the expression 'limits to the validity of contracts' or similar derivatives means limits to the validity of contracts on human tissue.

1.4 Methodology

This book combines different legal methods to determine the limits to the validity of contracts on human tissue.

As in many other cases in legal science, the determination of the limits to the validity of these contracts not only implied putting a puzzle together, but also, and perhaps more importantly, identifying the correct pieces and setting aside the incorrect ones. In this study, the different pieces correspond to the multi-level sources of law that constitute the legal framework for the analysis. In order to investigate the scope and content of these sources, I used a doctrinal research method. In this regard, I firstly identified the international and supranational legal documents and their interplay with the national legal systems chosen as case studies. Secondly, descending to the national level, this study did a detailed review of the national legislation, case law and corresponding scholarly literature. In this step, the absence of specific case law on the subject matter of this book was notorious. For this reason, only a few cases have been reported. Thirdly, this work assessed whether an analysis of examples from the contractual practice was possible. Although a few examples of contracts between first and subsequent recipients were found, it was conspicuously hard to find non-gratuitous contracts of this kind. The reason for this difficulty may possibly be explained by the, otherwise understandable, reluctance of the (pharmaceutical) industry to reveal to the public their contractual practices. The Annexes of this book contain the contracts found and analysed.

[21] See for example Young 2007, Young 2014, Young 2014(1).

Finally, the functional approach was used for the comparative analysis of the national legal systems of Italy and England.[22]

This research was completed on 1 September 2019. Later developments in case law and scholarly literature have only been considered in special cases.

1.5 Structure

This book is divided in seven Parts, each of them divided in different Chapters, Sections and Subsections.

Part 2 is devoted to the analysis of international and supranational law sources that, directly, or indirectly, limit the validity of contracts on human tissue. For this purpose, Chapter **2** explores fundamental or human rights legal sources, at the international or supranational level, which may be applicable in the legal systems of England & Wales and Italy. In the first place, Chapter **3** identifies the possible limits to the validity of contracts on human tissue stemming from international or supranational legal documents on data protection. In the second place, Chapter **3** analyses how, and to what extent, the national data protection regimes in Italy and England, strengthen, modify or derogate from the GDPR.
Part 3 and **Part 4** correspond, respectively, to the analysis of the national legal systems in Italy and England. In order to have an overall view of the legal sources available for the analysis of the limits to the validity of contracts, both parts begin with the description of the multi-level system of sources of law for the determination of such limits (Chapters **4** in Italy and **13** in England). Chapters 4 and 13 are significantly short in comparison to the other chapters of this book. Although visually inelegant, I decided to include the description of the multi-level system of sources of law in each national legal system as short Chapters to do not deviate from the structure of the other parts of this book.

Part 3 and **Part 4** follow, inasmuch as possible, the same internal structure. However, the differences between the applicable legal sources in Italy and England, and the differences in the effects of the same legal sources made it impossible to maintain a perfect specular relation between both Parts.
Part 3 on Italy includes the following Chapters: Chapter **5** on the general private law norms on the invalidity of contracts; Chapter **6** on the relevant constitutional norms and their effect on private relationships; Chapter **7** on Article 5 of the Italian Civil Code; Chapter **8** on Article 50 of the Italian Penal Code; Chapter **9** on the debate on the prohibition of financial gain from the human body and its parts; Chapter **10** on the validity of contracts on human tissue concluded

[22] For a critical assessment of the functional method see Michaels, 2019. For a recent introduction to the comparative legal systems see Zeno-Zencovich, 2019. For more information about the comparative method see Örücu, 2012.

between the first transferor and the first recipient for profit; Chapter **11** on Examples from the contract practice, and; Chapter **12** on some concluding remarks on the limits to the validity of contracts on human tissue under Italian law.

Part 4 on England includes the following Chapters: Chapter **14** on the Human Tissue Act 2004; Chapter **15** on consent for the removal of tissue from living persons in England & Wales; Chapter **16** on the common law doctrines on the invalidity of contracts; Chapter **17** on fundamental rights and their effect on private relationships in England & Wales and; Chapter **18** on examples from the contractual practice, and; Chapter **19** Concluding remarks on contracts on human tissue under the law of England and Wales.

The following couples of Chapters of the Italian and English Parts respectively are mirror chapters for the analysis of the limits to the validity of contracts on human tissue: Chapters **5** and **16**; Chapters **6** and **17**, Chapters **11** and **18** and; Chapters **12** and **19**. Furthermore, both parts discuss the issue of consent for the extraction of human tissue: Chapter **8** and Chapter **15** in Italy and England respectively. Finally, both parts discuss special legislation in relation to the disposition of the human body: in Italy, Chapter **7** on Article 5 of the Italian Civil Code and, in England, Chapter **14** on the Human Tissue Act 2004. The remaining differences between the two parts answer to the particularities of each national legal system.

Part 5 is devoted to the comparative analysis of the limits to the validity of contracts on human tissue in Italy and England, as complemented by the supranational law sources of the European Union. This Part does not mirror the structure of Parts 3 and Part 4 for two reasons. Firstly, to facilitate the comparative analysis of the different contracts on human tissue. Secondly, to mirror, section by section, the different contractual relation of the research questions.

Therefore, the structure of **Part 5** is as following: Section 20.2 deals with the comparative analysis of the types of contracts on human tissue that have been explicitly prohibited or allowed by law. As it will become apparent in the book, various limits to the validity of contracts on human tissue arising from the analysis of the different law sources are equally applicable to more than one of the three types of contracts considered by this work, i.e. gratuitous and non-gratuitous contracts between the first transferor and first recipient and contracts between the first and subsequent recipients. For this reason, Section 20.3 compares the limits to the validity of contracts on human tissue in the legal systems of Italy and England that are not specific to a particular type of contract by reason of their non-gratuity or by reason of the condition of the contractual parties. However, because the elements of non-gratuity of the contract, and the position of the contractual parties give rise to specific limits that demand an independent analysis, Sections 20.4 and 20.5 will compare the limits to the validity of non-gratuitous contracts and contracts between the first and

subsequent recipients respectively, insofar as they have distinctive traits and limits that deserve an independent treatment. The internal structure of these sections corresponds to the main points of convergence and divergence of the legal systems analysed (e.g. data protection, consent, human dignity).

Part 6 corresponds to the position of this book on some of the matters discussed in the previous parts. This Part is divided in two chapters. The first one (Chapter **21**) analyses, from a theoretical perspective, and without reference to any national law, two issues associated to the validity of gratuitous contracts on human tissue concluded between the first transferor and the first recipient: a) the form and validity of consent and b) the problems associated to the anonymization and commodification of tissue samples. The second chapter (Chapter **22**) focuses on three aspects of the validity of non-gratuitous contracts on human tissue concluded between the first transferor and the first recipient: a) the relation between autonomy and paternalism in this type of contract; b) The limits to paternalism and; c) Governance and self-governance for the protection of the interests and rights of the parties involved in contracting on human tissue.

Finally, **Part 7** presents a number of conclusions, recommendations and puts forward some ideas for a further debate on the issue of contracting on human tissue for research.

The **Annexes** include the contracts analysed in the chapters on examples from the contractual practice.

The Dutch **academic summary** of the book can be found after the Annexes.

Part 2

IMPACT OF INTERNATIONAL AND EUROPEAN LAW

2

Chapter 2

Limits to the use of human tissue in Italy and England & Wales under international and European human rights law

PART 2 IMPACT OF INTERNATIONAL AND EUROPEAN LAW

CHAPTER 2 Limits to the use of human tissue in Italy and England & Wales under international and European human rights law

2.1 Overview

The assessment of the validity of contracts on human tissue under a certain national law demands that not only domestic law sources, but also the international and supranational law sources applicable in the national legal system in question, are taken into account. More specifically, the determination of the limits to the validity of such contracts may depend on the direct and indirect application of international or European documents relating to human dignity, human rights, and other fundamental rights. The Universal Declaration of Human Rights (hereafter: UDHR),[23] the European Convention on Human Rights (hereafter: ECHR)[24] and its Protocols, the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereafter: Oviedo Convention)[25] and the Charter of Fundamental Rights of the European Union (hereafter: CFREU)[26] bear particular relevance for the discussion of the validity of contracts on human tissue. This chapter will address the vertical and horizontal effects of these international and EU law sources under Italian and English law in so far as relevant for the validity of contracts on human tissue.

Section 2.2 provides an overview of the mechanism for the incorporation of international law in Italy and England & Wales, with particular emphasis on the UDHR, the ECHR and the Oviedo Convention. Section 2.3 briefly addresses the vertical and horizontal effect of EU law. Section 2.4 focuses in particular on the horizontal effect of the Charter of Fundamental Rights of the European Union. Section 2.5 identifies the possible limits to the validity of contracts on human tissue under English and Italian law stemming from the relevant applicable provisions of the UDHR, the ECHR, the Oviedo Convention and the CFREU. However, this section does not deepen further into the question of how the

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[23] UN General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, 217 A (III)

[24] Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, Europ .T.S. No. 5; 213 U.N.T.S. 221.

[25] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine Oviedo*, 4.IV.1997, CETS 164 (thereafter: 'Oviedo Convention on Human Rights and Biomedicine 1997'). For full text see: <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm> last accessed 2 November 2019.
For an overview of the literature on the Oviedo convention see for example: Lawson, 2010; Adorno, 2009; McCrudden, 2008; Den Exter, 2010; Beyleveld and Brownsword, 1998.

[26] Charter of Fundamental Rights of the European Union (2012/C 326/02) Published in the Official Journal of the European Union C 326/391 the 26th of October 2012.

rights included in these provisions may constitute limits to the validity of such contracts. Chapters 6 and 17 on Italian and English law respectively will address this question.[27]

Section 2.6 provides some comparative remarks on the international and European human rights limits to the use of human tissue.

2.2 Incorporation of international law in Italy and England & Wales

The legal systems of Italy and England & Wales[28] are dualistic systems for what concerns the incorporation of international law into national law. A dualistic system requires the Parliament (or, in some cases, the Government) to enact a normative act with the same content as the international document.[29]

2.2.1 Italy

In Italy, the status of international norms depends on their type: for customary international law (*norme internazionali consuetudinarie*) different rules apply than for the law of treaties (*diritto internazionale pattizio*).

For what concerns customary international law, according to Article 10 par. 1 of the Italian Constitution (hereafter: Cost.), "Italian laws conform to the generally recognized norms of international law".[30] This Article exclusively allows the automatic and permanent incorporation in the Italian legal system of customary international norms: undisputedly, it does not deal with the effects of international treaties.[31]

For what concerns the law of treaties, according to Article 11 Cost, "Italy (…) agrees, on conditions of equality with other states, to the limitations of sovereignty necessary to create an order that ensures peace and justice among Nations; it promotes and encourages international organisations having such ends in view." [32] The interpretation of this Article with regard to the

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[27] See Part 4 Chapter 6 and Part 5 Chapter 17 on the effect of fundamental rights in private relations in Italian and English Law respectively.

[28] In order to avoid the constant alliteration of "England & Wales", unless otherwise specified, future references to England shall include also Wales.

[29] For Italy see, among others, Enc. giuridica Treccani. Available at: <http://www.treccani.it/enciclopedia/adattamento-del-diritto-interno-al-diritto-internazionale/> last accessed 14 November 2018, with further references. For England & Wales see Lytvynyuk, 2010, p. 192.

[30] Translation available at: <http://www.jus.unitn.it/dsg/pubblicazioni/costituzione/costituzione%20genn2008eng.pdf> Last accessed 9 September 2019. The original reads: "*L'ordinamento giuridico italiano si conforma alle norme del diritto internazionale generalmente riconosciute*."

[31] Panizza & Stradella 2013, p. 283; Favilli & Fusaro, 2007, p. 289.

[32] Translation available at: http://www.jus.unitn.it/dsg/pubblicazioni/costituzione/costituzione%20genn2008eng.pdf. Last accessed <2 November 2019>. The original reads: "*(L'Italia) consente, in condizioni di parità con*

incorporation of international treaties into Italian law was controversial for a long time. Until a reform of the Italian Constitution in 2001, it was a widespread opinion among Italian legal scholars that an international treaty has the same status as the norm that incorporates it into national law, e.g. a constitutional law, an ordinary Parliamentary statute or a Government decree.[33] According to this opinion, a posterior domestic law with the same or superior status could derogate from the norm of an international treaty previously incorporated into the Italian legal system. However, in 2001, the constitutional law 2001, n.3 (*L. Cost. 18 ottobre 2001, n.3*) modified Article 117 Cost., which regulates the legislative powers of the State and the Regions. According to subparagraph 1 of the modified Article 117, "(l)egislative power is exercised by the State and the Regions in compliance with the Constitution and the commitments deriving from Community law and international obligations (…)".[34] The new formulation of this Article led the Italian Constitutional Court in 2007[35] to maintain that the norms that incorporate international treaties have a stronger resistance force (*maggiore forza di resistenza*) to the abrogation by posterior domestic ordinary legislation.[36] According to this interpretation of the Constitutional Court, posterior domestic laws cannot abrogate the provisions that incorporate norms of international treaties. However, the latter norms remain at a sub-constitutional level and must conform to the Italian constitution in any case.[37]

Status of the UDHR

According to the prevailing Italian opinion,[38] the UDHR provisions constitute international consuetudinary law and falls within the scope of Article 10 Cost.

Status of the ECHR

The ECHR was incorporated in the Italian legal system by the law n. 848 of 4 August 1955[39] and entered into force the 25 October of the same year. Italian

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gli altri Stati, alle limitazioni di sovranità necessarie ad un ordinamento che assicuri la pace e la giustizia fra le Nazioni; promuove e favorisce le organizzazioni internazionali rivolte a tale scopo."

[33] Corte Costituzionale, 1990, p. 247 with reference to case law.

[34] "*La potestà legislativa è esercitata dallo Stato e dalle Regioni nel rispetto della Costituzione, nonché dei vincoli derivanti dall'ordinamento comunitario e dagli obblighi internazionali(…)*".

[35] Corte Costituzionale, sentenza 24/10/2007 n° 348. Official version available at <http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2007&numero=348>. Last accessed 2 November 2019.

[36] Ordinary legislation (*leggi ordinarie*) are domestic legislative acts without constitutional rank.

[37] Panizza and Stradella 2013, p. 284.

[38] Leopardi, 1997, p. 307-45; Cass. 14 June 2002, no 8503 (2003). However, some scholars have also sustained that only some of the rights contained in the UDHR can be considered consuetudinary international law. On this see Pisillo, 2013, available at < http://www.treccani.it/enciclopedia/diritti-umani-dir-int-protezione-internazionale_(Diritto-on-line)/> last accessed 16 December 2019.

[39] Legge 4 agosto 1955, n. 848. Ratifica ed esecuzione della Convenzione per la salvaguardia dei diritti dell'uomo e delle libertà fondamentali firmata a Roma il 4 novembre 1950 e del Protocollo addizionale alla Convenzione stessa, firmato a Parigi il 20 marzo 1952.

judges have paid particular attention to the issue of whether or not the EHCR has constitutional status.[40] After an initial phase when the ECHR was considered to have only the status of an ordinary Parliamentary statute, in 1993 the Constitutional Court,[41] followed later on by the civil sections of the *Corte di Cassazione* in 1998,[42] sustained that the ECHR has a privileged status in the Italian legal system. According to this approach, domestic law cannot modify the rights enshrined in the ECHR because the ECHR provisions "(…) impose real obligations on the Contracting States which are immediately binding and, after implementation into domestic law, are a source of rights and obligations for all subjects".[43]

Status of the Oviedo Convention

The Oviedo Convention was incorporated in the Italian legal system by the law n. 145 of 28 March 2001.[44] With this law, the Italian Parliament authorized the President to ratify the Oviedo convention (Article 1[45]) and conferred full and complete execution (*piena e intera esecuzione*) to the Convention and its additional protocol (Article 2[46]). However, the Italian government has not yet issued the necessary legislative decrees to adapt (Article 3[47]) the principles and norms of the Oviedo Convention to the Italian legal system. Although Italy has not ratified the Oviedo Convention, in the Ada Rossi and Others vs. Italy judgment the ECtHR indicated that it would take it into account for the analysis of the case.[48] Based on this decision, one may argue that the Oviedo Convention could be used by Italian courts and the ECtHR for analysis and decision of cases concerning human tissue.

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[40] On Italian literature on the ECHR see: Mori, 1983, p. 307-51; Barile, 1991, p. 119; Pace, 2001, p. 6-8; Alpa, 1999, p. 873-84.
[41] Corte Cost. 19 gennaio 1993, no. 10. See also, Corte Cost. 25 ottobre 2007, no. 348.
[42] Cass. Civ. 8 luglio 1998, n. 6672.
[43] Ibid.
[44] Legge 28 marzo 2001, n. 145.
[45] "*1. Il Presidente della Repubblica è autorizzato a ratificare la Convenzione del Consiglio d'Europa per la protezione dei diritti dell'uomo e della dignità dell'essere umano riguardo all'applicazione della biologia e della medicina: Convenzione sui diritti dell'uomo e sulla biomedicina, fatta a Oviedo il 4 aprile 1997, nonché il Protocollo addizionale del 12 gennaio 1998, n. 168, sul divieto di clonazione di esseri umani.*"
[46] "*Piena e intera esecuzione è data alla Convenzione e al Protocollo di cui all'articolo 1, a decorrere dalla data della loro entrata in vigore, in conformità a quanto disposto, rispettivamente, dall'articolo 33 della Convenzione e dall'articolo 5 del Protocollo.*"
[47] "1. *Il Governo è delegato ad adottare, entro sei mesi dalla data di entrata in vigore della presente legge, uno o più decreti legislativi recanti ulteriori disposizioni occorrenti per l'adattamento dell'ordinamento giuridico italiano ai princípi e alle norme della Convenzione e del Protocollo di cui all'articolo 1.*"
[48] *16 December 2008, Ada Rossi a.o. v Italy* (App nos 55185/08, 55483/08, 55516/08, 55519/08, 56010/08, 56278/08, 58420/08 and 58424/08)

2.2.2 England & Wales

The United Kingdom is seen as a dualist system with regard to the incorporation of international treaties into national law: international treaties need an act of Parliament before they have legal effect internally.[49]

Status of the UDHR

The UDHR has not been incorporated into national law by an act of Parliament and hence, it does not form part of English domestic law.[50]

Status of the ECHR

The ECHR was incorporated into the English legal system by the Human Rights Act 1998 (HRA) which came into force in 2000. The HRA gives effect to some of the provisions of the ECHR, namely Articles 2-12, Article 14, Articles 1-3 of the First Protocol, and Article 1 of the Thirteenth Protocol. It does not give effect to Article 13 (on remedies).[51]

The HRA has the status of a 'constitutional statute', which in practical terms means that it cannot be object of the doctrine of implied repeal.[52] This doctrine establishes that the rules of a *lex posterior* prevail over conflicting rules of an earlier statute.[53] In the case of the HRA, a posterior Act of the Parliament may not implicitly derogate its provisions. However, given the recent political developments in the UK, namely the victory of the conservative party in the general elections of 2015 and 2017 and the positive result in the Brexit referendum, it is uncertain whether the UK will remain part of the ECHR.[54] In fact, according to the Conservative and Unionist Party Manifesto 2017, the Conservative party "(…) will not repeal or replace the Human Rights Act while the process of Brexit is underway but (…) will consider our human rights legal framework when the process of leaving the EU concludes. (The Conservative Party) will remain signatories to the European Convention on Human Rights for the duration of the next parliament."[55]

Status of the Oviedo convention

The UK has neither signed, nor ratified the Oviedo Convention. However, one may argue that this instrument may have, at least, an interpretive value in this

[49] Lytvynyuk, 2010, p. 192.
[50] Hannum, 2014, p. 293.
[51] Section 1 HRA 1998.
[52] Oliver, 2007, p. 68
[53] Lytvynyuk, 2010, p. 192.
[54] For a discussion over the inconvenience of repealing the HRA 1998 see Gearty, 2016.
[55] Conservative and Unionist Party Manifesto 2017, p. 39, available at: https://www.conservatives.com/manifesto. On the recent developments regarding the intentions of the Conservative party to scrap the HRA see Colombi Ciacchi, 2017, 105-109.

country. Based on section 2(1)(a) of the HRA 1998, English courts have to take into account the jurisprudence of the ECtHR when solving a dispute where a ECHR right is involved. The ECtHR has increasingly referred to the Oviedo Convention in their rulings. The first time the Oviedo Convention was mentioned in the ECtHR case law, was in the case Cyprus v. Turkey.[56] In this case, Judge Marcus-Helmons, in a partly dissenting opinion, sustained: "With the rapid evolution of biomedical techniques, new threats to human dignity may arise. The Convention on Human Rights and Biomedicine, signed at Oviedo in 1997, seeks to cover some of these dangers."

The Oviedo Convention has since, repeatedly appeared in the case law[57] of the ECtHR.[58] Particularly important is the Glass case,[59] where the ECtHR sustained that the regulatory framework for consent in the UK is in no way inconsistent with the Oviedo Convention's provisions on consent.[60] According to a scholarly position, in this judgment, the ECtHR is reviewing the British regulatory framework on consent, even though the UK has not signed or ratified the Oviedo Convention.[61]

2.3 Vertical and horizontal direct effect of EU law

In the Van Gend & Loos judgement,[62] the Court of Justice established that EU primary legislation (e.g. the Treaties) has direct effect if the legislative obligation is precise, clear, and unconditional and does not call for additional measures. According to the principle of direct effect, European law directly creates not only obligations for EU member states, but also rights for individuals. This principle entitles individuals to invoke a EU legislative provision before a national or European court. [63] Furthermore, the view has been expressed that the direct effect is not always linked with the principle of precedence (as in the Van Gend & Loos), for example, when an employee can invoke a EU principle or provision to prove that the employment contract with a public body conflicts with the principle or provision and is therefore invalid.[64]

One speaks of vertical direct effect with regard to the effect of EU law on the relations between a state actor and an individual, and of horizontal direct effect

[56] 10 May 2001, *Cyprus v. Turkey* (App. No. 25781/94).
[57] See for example the cases: 8 August 2012 *Costa and Pavan v Italy* (App. No 54270/10); 10 April 2007, *Evans v UK* (App. No. 6339/05); 8 July 2004 *Vo v France* (App. No. 53924/00).
[58] For works on the relation between the ECHR, the ECthR and the Oviedo convention see Seatzu & Fanni, 2015; Lawson, 2010.
[59] 9 March 2004, *Glass v the United Kingdom* (App. No 61827/00).
[60] Ibid, para. 75.
[61] Nys, 2009. Available at: <http://www.coe.int/t/dg3/healthbioethic/Activities/10th_Anniversary/Herman%20Nys.pdf> Last accessed 2 November 2019.
[62] Case C- 26/62 *Van Gend & Loos v Netherlandse Administratie der Melastingen* [1963] ECR 1.
[63] Ibid.
[64] Hartkamp, 2012, p. 13 with further references.

for the effect of EU law on relations between natural and/or legal persons.[65] The ECJ has maintained that a treaty provision can produce direct horizontal effect between private individuals (e.g. Article 119 EEC then, Article 143 TFEU).[66]

The principle of direct effect also relates to secondary legislation (regulations and directives), but its applicability depends on the type of the act. Regulations have complete direct effect. Directives must be transposed by the EU countries into their national legal systems. In the Van Duyn case,[67] the Court of Justice maintained that a directive might have direct vertical effect if its provisions are precise, clear, and unconditional, and when a EU member state has not transposed the directive by the deadline.[68] Opinions and recommendations do not have direct effect because they do not have legal binding force.[69]

2.4 Horizontal effect of the Charter of Fundamental Rights of the EU

According to Article 6 of the TEU, the CFREU has the same legal effects as the Treaty between member states. The CFREU included the rights enshrined in the ECHR and recognized a number of social and economic rights inspired by the European Social Charter of the Council of Europe.[70]

While compliance with human rights is a requirement for the legality of EU acts, neither public authorities nor private persons can invoke the CFREU as the sole basis of a legal claim. This argument is based on the wording of Article 51 CFREU, according to which "(t)he provisions of this Charter are addressed to the institutions and bodies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law. They shall therefore respect the rights, observe the principles and promote the application thereof in accordance with their respective powers", and Article 6 TEU, according to which the provision of the CFREU "shall not extend in any way the competences of the Union (…)". On the basis of Article 6 par. 2 and 3 TEU, the Court of Justice of the European Union (CJEU) and national courts are under a duty to interpret EU provision in a way that is compatible with the rights enshrined in the CFREU.[71]

On the direct horizontal effect of the CFREU, in the Kücükdeveci[72] case, the CJEU initially recognized the direct horizontal effect of Article 21. Later on, in the

[65] Gabriele & Celotto, 2001, p. 73.
[66] Case C- 43/75 *G. Defrenne v SABENA* [1976] ECR 455
[67] Case C- 41/74 *Yvonne van Duyn v Home Office* [1974] ECR 133.
[68] Giliker, 2014, p. 10
[69] Gabriele & Celotto, 2001, p. 85.
[70] Collins, 2014, p. 31.
[71] Collins, 2014, p. 31.
[72] Case C-555/07. *Seda Kücükdeveci v Swedex GmbH & Co. KG.Judgment*, EU:C:2010:21.

Egenberger[73] and IR[74] cases, the CJEU recognized direct horizontal effect to Article 21 in combination with Article 47. More recently, in the Bauer[75] case, the CJEU acknowledged the direct effect of article 31(2) CFREU. In this judgment, the Court also beautifully precised that Article 51(1) does not exclude that some CFREU provisions create direct obligations for private parties. In contrast, in the AMS case the CJEU denied the direct effect of Article 27.[76]

According to some scholars, some other provisions of the CFREU are also capable of being applied directly to private parties. In particular, Articles 24, 28, 30, 31 (1) and 33(2) are also potentially capable of having direct horizontal effect.[77]

2.4.1 Italy

With regard to the effect of the CFREU on private relationships, Italian scholars have argued that it has, at least, an interpretative value.[78] More recently, following the cases of the CJEU that granted direct horizontal to some of the provisions of the CFREU, Italian scholars have followed suit,[79] and at least one scholarly position has argued for the full (*piena*) "indirect" (*mediata*) effect of CFREU rights through the application of national norms and clauses with undetermined content, e.g. good faith or the protected interest in the contract (*interesse meritevole di tutela del contratto*).[80]

However, the references to the CFREU by Italian judges are scarce. The first reference to the CFREU by an Italian court was the order of 11 April 2000 of the Rome Court of Appeal.[81] In 2002 (thus before the CFREU became legally binding), the Constitutional Court[82] referred to the Charter as an expression of the principles common to the European legal systems.[83] Since the Charter at the

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[73] Case C-414/16 *Vera Egenberger v Evangelisches Werk für Diakonie und Entwicklung e.V.*, EU:C:2018:257. On the Egenberger case see: Colombi Ciacchi, 2018, 207-211.
[74] Case C-68/17. *IR v JQ*. EU:C:2018:696
[75] Case C- 569/16. *Stadt Wuppertal v Maria Elisabeth Bauer and Volker Willmeroth v Martina Broßonn,* EU:C:2018:871.
[76] Case C‑176/12. *Association de médiation sociale v Union locale des syndicats CGT and Others*. EU:C:2014:2.
[77] Colombi Ciacchi, 2014, p. 119.
[78] Sucameli, 2007, p. 145.
[79] Genussa, 2019, p. 459. On very recent Italian literature on the relationship between fundamental rights and private law see Gaggia & Resta (eds), 2019. On the direct horizontal application of the principle of non-discrimination on the grounds of religion see Zaccaroni, 2019. On the matter of direct horizontal application of fundamental rights in matters pertaining to digital privacy see Pollicino, 2018. Finally, on the direct effect of CFREU rights in the aftermath of the Vera Egemberger case see Cappuccio, 2018, p. 708. Regarding recent developments on the direct horizontal effect of EU law fundamental rights see Colombi Ciacchi, 2019.
[80] Libertini, 2019, p. 78.
[81] Corte d'Appello di Roma, Ordinanza 11 aprile 2002. Available at: < http://www.dirittiuomo.it/corte-d'appello-di-roma>.
[82] Corte Cost. 11 aprile 2002, n. 135.
[83] [83] Corte Cost. 11 aprile 2002, n. 135: "(…) *per il suo carattere espressivo di principi comuni agli ordinamenti europei*".

time was not legally binding, the Court could not recognize its legal efficacy (*efficacia giuridica*): it maintained that the CFREU had a 'weak' interpretative value, in the sense that it strengthened the line of reasoning of the judge.[84]

Both the Italian Court of Cassation and Constitutional Court have applied the CFREU after it became legally binding. In 2010, in a case concerning non-patrimonial damages, the Court of Cassation sustained that "(…) the referring judges must seek inspiration in the principles of Article 1 of the Charter that regulates the value of human dignity (which also includes the professional dignity) and Article 15 of the Charter that regulates professional freedom as a inviolable right (…)" and that "the Court of Cassation´s uniform interpretation of the law includes also the interpretative process to conform national and constitutional laws to the non conflicting but promoting principles of the Treaty of Lisbon and the Charter of Nice (…)".[85]

In 2011, the Italian Court of Cassation, in a case involving the assessment of moral damages in relation to the violation of the right to health, acknowledged a close link between Article 2 Cost. and Article 1 CFREU. This judgment also explicitly stated that human dignity is the greatest expression of physical and moral integrity.[86]

Moreover, in 2011, the Italian Constitutional Court confirmed the principle (already deducible from Article 51 of the Charter) according to which a prerequisite for the applicability of the CFREU is that the case before the court is governed by EU law and not only by national norms lacking any relation with EU law. [87]

Italian literature deduces from the abovementioned case law a trend in Italian jurisprudence towards the fusion of the different constitutional levels (national level and EU level), also in decisions on litigations between private parties.[88]

2.4.2 England & Wales

Protocol 30 to the TEU,[89] on the application of the Charter of Fundamental Rights of the European Union to Poland and the United Kingdom,[90] allowed the UK to

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[84] Cfr. Celotto, 2003, p. 33; Sucameli, 2007, p. 146.

[85] Cass. Civ.. 2 febbriao 2010 n. 2352: "*I giudici del rinvio dovranno ispirarsi anche ai principi di cui all'art. 1 della Carta, che regola il valore della dignità umana (che include anche la dignità professionale) ed all'art. 15 che regola la libertà professionale come diritto inviolabile* (…)""(…) *la filonomachia della Corte di Cassazione include anche il processo interpretativo di conformazione dei diritti nazionali e costituzionali ai principi non collidenti ma promozionali del Trattato di Lisbona e della Carta di Nizza* (…)".

[86] Cass. Civ. 16 giugno 2011 n. 18641 with reference to Cass. Civ. 12 dicembre 2008 n. 29191.

[87] Corte Cost. 7 marzo 2011, n. 80/ with reference to Corte Cost. 8 marzo 2010, n. 93.

[88] Bronzini, 2012, p. 21.

[89] The Articles of the Protocol read: "Article 1 1. The Charter does not extend the ability of the Court of Justice of the European Union, or any court or tribunal of Poland or of the United

opt-out from the CFREU.[91] This Protocol intends to work as a legally binding instrument that precludes the creation of new enforceable rights to those already existing under UK laws.[92]

2.5 International and EU law provisions that may impact the validity of contracts on human tissue in Italy and England & Wales

2.5.1 Preliminary remarks

This section identifies the provisions of the UDHR, the ECHR, the Oviedo Convention and the CFREU that, because of their direct effect or interpretative value, are relevant to the validity of contracts on human tissue. This succinct outline of the relevant provisions is intended to provide the reader with a general overview of the rights incorporated in these international and European instruments that may impact the validity of these contracts. For this purpose, and for methodological reasons, this subsection proposes clustering the provisions of the UDHR, the ECHR, the Oviedo Convention and the CFREU according to their subject matter. The following subsections correspond each to one of the different clusters: 2.5.2 Dignity, equality and respect for human rights; 2.5.3 Respect for private life and protection of personal data; 2.5.4 Consent and integrity of the person and, 2.5.6 Miscellaneous provisions.

2.5.2 Dignity, equality and respect for human rights

The following articles of the UDHR, ECHR, Oviedo Convention and CFREU belong to the proposed cluster of provisions that aim at the protection of (human) dignity, and the promotion and protection of human rights for all human beings: Article 1 UDHR on dignity and equality of rights of human beings,[93] Article 1 ECHR on the obligation to respect human rights,[94] the preamble of the Oviedo

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Kingdom, to find that the laws, regulations or administrative provisions, practices or action of Poland or of the United Kingdom are inconsistent with the fundamental rights, freedoms and principles that it reaffirms.2. In particular, and for the avoidance of doubt, nothing in Title IV of the Charter creates justiciable rights applicable to Poland or the United Kingdom except in so far as Poland or the United Kingdom has provided for such rights in its national law.
Article 2. To the extent that a provision of the Charter refers to national laws and practices, it shall only apply to Poland or the United Kingdom to the extent that the rights or principles that it contains are recognised in the law or practices of Poland or of the United Kingdom."

[90] Protocol (no 30) on the application of the Charter of Fundamental Rights of the European Union to Poland and the United Kingdom, OJ C-306/157, of 17th December 2007.

[91] Youngs, 2016, p. 561.

[92] Douglas-Scott, 2011, p. 653. For an extensive analysis if this protocol see in particular Bernard, 2008.

[93] Article 1 UDHR: "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood."

[94] Article 1 ECHR: "The High Contracting Parties shall secure to everyone within their jurisdiction the rights and freedoms defined in Section I of this Convention."

Convention,[95] Article 1 Oviedo Convention (on the purpose and object of the convention),[96] Article 2 Oviedo Convention on the primacy of the human being,[97] and Article 1 CFREU on human dignity.[98]

One may argue that these articles are relevant for the validity of contracts on human tissue because on the grounds of a violation of human dignity or any other fundamental right a contract –or a contractual clause– could be declared illegal, contrary to public policy or to public order.[99] The invalidity of such contracts would be the result of the indirect horizontal effect of international or EU law via the interpretation of national law rules on illegality, immorality or public policy in general.

2.5.3 Respect for private life and protection of personal data

The following articles are part of the cluster of provisions relating to the protection of the private life of the individual and its personal data: Article 8 ECHR on the right to respect for private and family life,[100] Article 10 Oviedo Convention on private life and right to information,[101] Article 7 CFREU on the

[95] Preamble to the Oviedo Convention: "The member States of the Council of Europe (…) Convinced of the need to respect the human being both as an individual and as a member of the human species and recognizing the importance of ensuring the dignity of the human being; Conscious that the misuse of biology and medicine may lead to acts endangering human dignity; (…) Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine, Have agreed as follows (…)"

[96] Article 1 Oviedo Convention: "Purpose and object: Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention."

[97] Article 2 Oviedo Convention: "The interests and welfare of the human being shall prevail over the sole interest of society or science."

[98] Article 1 CFREU: "Human dignity is inviolable. It must be respected and protected."

[99] This idea is developed further in later sections of this book (e.g. section 6.5 and 7.4).

[100] Article 8 ECHR: "1. Everyone has the right to respect for his private and family life, his home and his correspondence. 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

[101] Article 10 Oviedo Convention: "1 Everyone has the right to respect for private life in relation to information about his or her health. 2 Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed. 3 In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient."

right to respect for private and family life,[102] and Article 8 CFREU on the protection of personal data.[103]

Human tissue is the vessel of sensitive genetic and health data of an individual. Thus, the wrong recollection, processing or management of these data may constitute a violation of the right to the private life of a person. As a consequence, one may argue that a contract on human tissue that does not include the sufficient safeguards for the protection of the personal data and private life of the person may be declared invalid.[104] Theoretically, the invalidity of such contract could be the result of both the direct and the indirect horizontal effect. However, the indirect horizontal effect has a much broader scope of application since it can be used when applying whatever national legal ground of invalidity of a contractual agreement. In contrast, direct horizontal effect comes into consideration when an interpretation of national law in the light of supranational law is not possible.

2.5.4 Consent and integrity of the person

Consent is, generally speaking, a necessary requirement for a lawful intervention on the person's physical integrity or health.[105] In the absence of consent, or in cases when consent is not complete, such intervention may be tainted with illegality. For this reason, a contract on human tissue that does not meet the necessary requirements of consent may be declared invalid.[106] Such invalidity could stem from the indirect horizontal effect of supranational law via the interpretation of national law on the validity of the contracts. Therefore, the following articles may be relevant for the determination of the limits to the validity of contracts on human tissue: Article 5 Oviedo Convention (on consent),[107] and Article 3 CFREU (on the right to the integrity of the person).[108]

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[102] Article 7 CFREU: "Everyone has the right to respect for his or her private and family life, home and communications."

[103] Article 8 CFREU: "1. Everyone has the right to the protection of personal data concerning him or her. 2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified. 3. Compliance with these rules shall be subject to control by an independent authority."

[104] This idea is developed in depth in Chapter 20.3.2.

[105] Beyleveld and Brownsword, 2007, p. 16.

[106] For a complete analysis of consent as limit to validity of contracts on human tissue see section 20.3.5.

[107] Article 5 Oviedo Convention: "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time."

[108] Article 3 CFREU: "1.Everyone has the right to respect for his or her physical and mental integrity. 2. In the fields of medicine and biology, the following must be respected in particular: -the free and informed consent of the person concerned, according to the procedures laid down by law, -the prohibition of eugenic practices, in particular those aiming at the selection of

2.5.5 Miscellaneous provisions

Other international and European law provisions may be relevant for the determination of the limits to the validity of contracts on human tissue but cannot be clustered in a specific group. The following Chapters of the Oviedo Convention bear relevance as a whole for the identification of such limits: Chapter IV on the human genome, Chapter V on scientific research and Chapter VII on the prohibition of financial gain and disposal of a part of the human body.

Moreover, Article 17 CFREU (on the right to property)[109] may be also relevant for the determination of property rights arising from a contract on human tissue.

2.6 Concluding remarks on the international and European human rights limits to the use of human tissue

Both the Italian and UK legal systems are dualistic systems in relation to the incorporation of international law into national law. However, the Italian legal system differentiates between customary international law and the law of treaties. While the Italian Constitution (Article 10 par. 1 Cost.) allows for the automatic and permanent incorporation of consuetudinary international law into national law, international treaties do require a separate act for their incorporation. The latter act cannot be object of the doctrine of implied repeal,[110] and remains at a sub-constitutional level and must conform to the Italian constitution in any case.

The status of the different international and supranational law documents varies among the Italian and English legal system:

The UDHR is regarded in Italy as consuetudinary law and falls within the scope of Article 10 par. 1 Cost. In England, on the contrary, the UDHR has not been incorporated into national law and does not form part of English domestic law.

The ECHR has been incorporated into the Italian and English legal systems by the law n. 848 of 4 August 1955 and the HRA 1998 respectively. In both legal systems the ECHR has a special status. In Italy, domestic law cannot modify the

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persons, -the prohibition on making the human body and its parts as such a source of financial gain, -the prohibition of the reproductive cloning of human beings."

[109] Article 17 CFREU: ""1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest. 2. Intellectual property shall be protected."

[110] Italian scholars indicate that these act have a "*maggiore forza di resistenza*", which in literal words means "stronger resistence force", to indicate that the incorporating act cannot be abrogated by an act of the same constituional rank.

rights enshrined in the ECHR. In England, the HRA 1998 is considered a constitutional status and cannot be the object of the doctrine of implied repeal.

With regard to the Oviedo Convention there are substantial differences between the Italian and the English legal systems. In Italy, the Oviedo Convention was incorporated by the law n. 145 of 28 March 2001, but the necessary legislative decrees for its adaptation to the Italian legal system have not yet been issued. In England & Wales, the Oviedo convention has neither been signed, nor ratified. However, since English courts have to take into account the case law of the ECtHR (see section 2(1)(a) HRA 1998), and the ECtHR has increasingly referred to the Oviedo Convention in its rulings, one may argue that this document has at least an interpretative value in England.

For what concerns the effect of the CFREU on private relationships in Italy, scholars have argued that it holds at least an interpretative value. Moreover, from a series of judicial decisions, commentators have identified a trend in Italian jurisprudence towards the fusion of the national and EU constitutional levels for what concerns the references made to fundamental rights by civil courts. The UK, on the contrary, with Protocol 30 to the TEU, opted out from the application of the CFREU.

More generally, there is a wide consensus among Italian scholars that supranational legal documents on fundamental rights and human dignity have an important influence on the interpretation of national law. However, there is no case law on the Italian or EU level that leads to the direct horizontal application of a supranational norm in matters related to acts of disposition of the human body. Only in rare occasions have Italian courts granted horizontal effect to other sources different than the Constitution. As a consequence, it does not seem likely that Italian courts will directly apply a supranational norm on human dignity or fundamental rights to enforce a limit to the validity of a contract on human tissue. However, Italian courts, in adjudicating such contractual relationships, could arguably also give direct horizontal effect of a supranational norm on human dignity or fundamental rights.

In England & Wales it seems unlikely that judges will grant horizontal effect to supranational legal documents on fundamental rights other than the ECHR, as incorporated in the HRA 1998. In some cases human rights documents have not been incorporated into national law at all (e.g. UDHR), and in some other cases, the UK has decided to opt-out from them (e.g. CFREU). However, because English courts have to take into account the case law of the ECtHR when solving a case where a ECHR right is involved, supranational legal documents like the Oviedo Convention still hold an interpretative value in solving human rights cases between private parties.

For these reasons, one may argue that in Italy, the relevant norms of the UDHR, ECHR, the Oviedo Convention and the CFREU constitute limits to the validity of contracts on human tissue. In England, arguably only the relevant provisions of the HRA 1998 and the Oviedo Convention have an effect for the interpretation or determination of the validity of such contracts.

Arguably, these limits have a double function. On the one hand, such limits reinforce the limits already existing under national law. In this sense, their value is not only formal, since they stem from fundamental rights recognized in supranational law, but also substantial, since they contribute to the interpretation of national law rules. On the other hand, such limits may protect interests that are not adequately protected under national law.

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Chapter 3

Limits to the use of human biological samples under the General Data Protection Regulation

CHAPTER 3 Limits to the use of human biological samples under the General Data Protection Regulation

3.1 Overview

Because the term used by data protection scholars and EU documents on data protection is 'human biological samples' and not 'human tissue', section 3.2 defines and explores the notions of health, genetic and sensitive data. Section 3.3 provides a general overview of the European data protection model for the regulation of biomedical research. Section 3.4 analyses, in particular, the relevant provisions of the Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons and on the free movement of such data (hereafter General Data Protection regulation or GDPR).[111] Section 3.5 outlines how this European data protection model has been implemented in Italy and England & Wales and which limits to the use of human biological samples can be derived from it. Section 3.6 provides some preliminary comparative conclusions.

3.2 Human biological samples and sensitive data

Human biological samples contain useful genetic and health data for research.[112] These data are regarded as sensitive data, i.e. data that are suitable to reveal the racial and ethnic origin of a person, her health status or her sexual orientation. For these reasons, genetic and health data are worthy of particular protection by the legal system.[113]

Health data are data that refer to the mental or physical well-being of a natural person.[114] Genetic data are used, particularly, in the fields of genetics, genomics and pharmacogenomics. The notion of research in genetics, genomics and pharmacogenomics makes reference to a vast diversity of scientific studies on single genes or the entire human genome to understand the aetiology of numerous diseases (unifactorial or multifactorial) or the individual response to medications.[115]

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[111] REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L. 119/1.

[112] On the use of the term 'human biological samples' see Part 1, Chapter 1 on Delimitation and terminology.

[113] De Franco, 2007, p. 1347.

[114] According to the World Health Organization (WHO), health "is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Definition available at: <https://www.who.int/about/who-we-are/frequently-asked-questions> last accessed 2 November 2019.

[115] Lattanzi, 2011, p. 319.

From a biological point of view, genetic data can be defined as data that refer to the genetic makeup of an individual and are relevant for the study of genetic diseases since they can identify a person carrying certain pathology or a genetic predisposition to one or more diseases. From a legal point of view, genetic data are considered personal data that allow the identification of a given person.

Genetic data have at least three particular characteristics that make them different from other types of personal information.[116] Firstly, genetic data are suitable not only to identify an individual, but also to link the person to a given group (a parental group). For this reason, both the individual and the biological group (e.g. family, race) may have interests in how the genetic data are treated and as a consequence, potential conflict of interests may arise between the members of the same biological group.[117] Secondly, genetic data have a predictive nature, i.e. they can provide information about the future state of health of the person or a member of the biological group. Thirdly, genetic data are as a general rule inalterable: they remain the same during the whole life of the individual.[118]

Even though it is undeniable that biomedical research may result in immense benefits for mankind, it is equally uncontested that the risks to the person's privacy and self-determination typically associated to this type of research are high. This is particularly true in the cases when research is carried out on large repositories of human biological samples and genetic and other health data that are able to provide a complete profile of the person's most private characteristics.[119]

3.3 The European data protection model

The determinant role of personal information in genetic research led European legislators, courts and scholars to formulate a model pivoted on the protection of personal data. Under this model, the physical or "material" dimension of the human biological samples does not come into play immediately. The immediately relevant aspect is the information that can be retrieved from them: human biological samples assume the role of data shells or vehicles. From this perspective, a scholarly opinion proposes that the adequate normative framework to regulate the use of human biological samples should come closer to the legal regime of personality rights and not to the one of property rights.[120] This scholarly opinion, however, maintains that the legal regime for the protection of personal data should not be directly applicable to human biological samples: only the principles that regulate the circulation and conservation of

[116] Stefanini, 2008, p. 3.
[117] De Franco, 2007, p. 1348.
[118] For a complete characterization of the notion of gentic data see Taylor, 2012.
[119] Stefanini, 2009, p. 7
[120] Lattanzi, 2011, p. 329.

human biological samples should not be too different from the principles concerning the protection of personal data.[121] Others have proposed to extend the protection afforded by data protection laws to human biological samples.[122]

At the European level several legal documents regulate the use of genetic or personal data and the protection of the person in relation to the use of these data. In general, both Article 8(1) CFREU and 16(1) TFEU state that "everyone has the right to the protection of personal data concerning him or her". More specifically, Articles 3 and 21 of the CFREU prohibit "eugenic practices, in particular those aiming at the selection of persons" and "(a)ny discrimination based on (…) genetic features." Articles 5 and 11 of the Oviedo Convention also bear relevance for the protection of the person in relation to the use of its genetic data. Article 5 states that "(a)n intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks." Article 11 prescribes that "(a)ny form of discrimination against a person on grounds of his or her genetic heritage is prohibited."

Other important documents for the protection of personal data for the purpose of this book are the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data 1981 [123] (hereafter, Strasbourg Convention) and the GDPR.

The Strasbourg Convention was signed and ratified by both Italy and the UK. Article 6 of this Convention, regarding special categories of data, prescribes that: "(p)ersonal data revealing racial origin, political opinions or religious or other beliefs, as well as personal data concerning health or sexual life, may not be processed automatically unless domestic law provides appropriate safeguards. The same shall apply to personal data relating to criminal convictions." This convention did not include any references to genetic data. However, genetic data may be included within the broader category of health data. Compared to the GDPR, the Convention does not provide any strengthened or particular protection to the rights of the individual. For this reason, the Strasbourg Convention will not be further discussed in this book.

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[121] The Article 29 Data Protection Working Party was set up under the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Official Journal No. L 281 of 23.11.1995, p. 31, available at: http://europa.eu.int/comm/internal_market/en/media/dataprot/index.htm

[122] Taylor, 2012, 159.

[123] Treaty 108, Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, CETS No. 108, Strasbourg, 28 January 1981.

The GDPR repeals the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (hereafter Directive 95/46/CE).[124] The GDPR entered into force on May 24 2016, and it applied from 25 May 2018.[125]

Before the coming into force of the General Data Protection Regulation, the Strasbourg Convention and the Directive 95/46/CE were considered to be the cornerstones of the European notion of privacy.[126] Under these documents, the notion of privacy is understood as the power of the individual to control the information about her by defining rights and imposing obligations on those who intend to treat or process the information. Now that the General Data Protection Regulation has repealed the Directive 95/46/CE one could argue that the Strasbourg Convention and this new Regulation constitute the core of the European data protection system. Moreover, according to the General Data Protection Regulation the objectives and principles of the Directive 95/46/CE remain sound.

3.4 The General Data Protection Regulation

-Scope

The General Data Protection Regulation lays down the rules relating to the protection of natural persons with regard to the processing of personal data and protects fundamental rights and freedoms of natural persons, in particular, their right to personal data.[127]

-Definitions

Article 4 GDPR defines, among others, the notions of processing, restriction of processing, profiling, controller, processor, recipient, third party, consent, and personal data breach. Particularly relevant for the scope of this book are the notions of personal data, genetic data and health data.[128]

Article 4(1) GDPR defines personal data as: "any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical,

[124] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. OJ L281, 23/11/1995, p. 3.1-50.
[125] Article 99 General Data Protection Regulation.
[126] Stefanini, 2008, p. 17.
[127] Article 1 GDPR.
[128] On the relevance of this notions see section 3.2 of this Chapter.

physiological, genetic, mental, economic, cultural or social identity of that natural person."[129]

Article 4(13) GDPR states that genetic data means: "personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question."[130]

Article 4(15) defines data concerning health as "personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status". [131]

Furthermore, the GDPR defines the notion of pseudonymisation[132] (previously not included in the Directive 95/46/CE), and prescribes, as a general rule, that pseudonymised data should be considered personal data.[133] In the same line, Recital 26 prescribes that the principles of the GDPR should not apply to anonymous information.[134]

-*Principles of the GDPR*

The General Data Protection Regulation confirms the principles embodied in the Directive 95/46/CE. According to Article 5(1) GDPR, the processing of personal data shall conform to the principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation and integrity and confidentiality.[135]

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[129] Article 4(1) GDPR.
[130] Article 4(13) GDPR.
[131] Article 4(15) GDPR.
[132] Article 4(5) GDPR: "'pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person"
[133] Recital 26 GDPR: "The principles of data protection should apply to any information concerning an identified or identifiable natural person. Personal data which have undergone pseudonymisation, which could be attributed to a natural person by the use of additional information should be considered to be information on an identifiable natural person(…).
[134] Recital 26 GDPR "(…) The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes."
[135] Article 5(1) GDPR: "Principles relating to processing of personal data (a) processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency'); (b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation'); (c) adequate, relevant and limited to what is necessary in

In particular, Article 5(1)b on the purpose limitation principle prescribes that further processing for archiving purposes in the public interest, or scientific purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes. Recital 50 GDPR further specifies that the processing for compatible purposes does not require a separate legal basis from the one that allowed the collection of data in the first place.[136] Furthermore, recital 156 GDPR requires that the controller assesses whether anonymous data cannot be used instead.[137] Article 89(1)[138] confirms the necessity of making sure that anonymous data could not be used instead and prescribes other necessary safeguards for the rights and freedoms of the data subject when further processing for archiving purposes in the public interest, or for scientific research purposes. These safeguards are technical and organisational measures that must be in place to respect the principle of data minimisation (e.g. pseudonymisation measures).

-Lawful processing of personal data under the GDPR

Article 6 of the General Data Protection Regulation states the cases in which processing shall be lawful. The following bear particular relevance for the subject matter of this book:

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relation to the purposes for which they are processed ('data minimisation'); (d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy'); kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation'); processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality')."

[136] Recital 50 GDPR: "The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required (…)."

[137] Recital 156 GDPR: "The further processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which do not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data)."

[138] "Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner."

- the data subject has given consent to the processing of her personal data for one or more specific purposes;
- processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
- processing is necessary to protect the vital interests of the data subject or of another natural person;
- processing is necessary for the performance of a task carried out in the public interest; and
- processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child. [139]

-Prohibition and exceptions to the processing of special categories of personal data

Furthermore, Article 9.1 GDPR[140] prohibits the processing of special categories of personal data, including genetic and data concerning health.[141] However, Article 9.2[142] contains a number of exceptions to this prohibition, including the

[139] Article 6 GDPR, entitled "Lawfulness of processing", reads: "1. Processing shall be lawful only if and to the extent that at least one of the following applies: (a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes; (b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract; (c) processing is necessary for compliance with a legal obligation to which the controller is subject; (d) processing is necessary in order to protect the vital interests of the data subject or of another natural person; (e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller; (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child. Point (f) of the first subparagraph shall not apply to processing carried out by public authorities in the performance of their tasks.

[140] Article 9.1 reads the following: "Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited (…)".

[141] Dove, Thompson, Knoppers, 2016, p. 1374. On the relation between research on genetic data and human research see Pormeister, 2018.

[142] Article 9.2 states: "2. Paragraph 1 shall not apply if one of the following applies: (a) the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject; (b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law in so far as it is authorised by Union or Member State law or a collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject; (c) processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent;

explicit consent of the data subject to the processing of genetic data for one or more specific purposes, and the cases in which processing is necessary for scientific research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law.[143]

-Consent

Regarding the first aforementioned exception (consent), Article 4(11) GDPR defines it as: "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her." Article 7 GDPR lays down four conditions for consent. Firstly, the controller[144] shall be able to demonstrate that the person has consented to processing of her personal data. Secondly, if the data subject's consent is given in the context of a written declaration, which also concerns other matters, the request for consent shall be presented in a manner that is clearly distinguishable from the other matters. Thirdly, the data subject shall have the right to withdraw her consent at any time. Fourthly, when assessing whether consent is freely given, utmost account shall be taken of whether the performance of a contract is conditional on consent to the processing of personal data that is not necessary

(d) processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects; (e) processing relates to personal data which are manifestly made public by the data subject; (f) processing is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity; (g) processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject; (h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3; (i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy; (j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

[143] For an analysis of the research exception to consent in the GDPR see Pormeister, 2017.

[144] According to Article 4.7 of the General Data Protection Regulation, the controller is the person who determines the purposes and means of the processing of personal data.

for the performance of that contract.[145] Furthermore, Recital 33 GDPR admits that in scientific research it is often not possible to fully identify the purpose of personal data processing at the time of data collection.[146] For this reason, Recital 33 allows data subjects to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. According to this Recital, data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.[147] Furthermore, scholars have argued that Recital 33 facilitates flexibility in the interpretation of the notion of consent for scientific research and brings this interpretation closer to the practice in some member States.[148]

-Information duties

Finally, Article 13[149] GDPR lists the information to be provided by the controller to the data subject when the data are collected from the data subject, which

[145] Article 7 GDPR states that: "1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data. 2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding. 3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent. 4. When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.

[146] Recital 33 GDPR: "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose."

[147] Dove, Thompson, Knoppers, 2016, p. 1374.

[148] See Wellcome Trust, 2016, Analysis research and the general data protection regulation, p. 6 available at: <https://wellcome.ac.uk/sites/default/files/new-data-protection-regulation-key-clauses-wellcome-jul16.pdf > last accessed 2 November 2019.

[149] Article 13 GDPR: "Information to be provided where personal data are collected from the data subject 1. Where personal data relating to a data subject are collected from the data subject, the controller shall, at the time when personal data are obtained, provide the data subject with all of the following information: a) the identity and the contact details of the controller and, where applicable, of the controller's representative; (b) the contact details of the data protection officer, where applicable; (c) the purposes of the processing for which the personal data are intended as well as the legal basis for the processing; (d) where the processing is based on point (f) of Article 6(1), the legitimate interests pursued by the controller or by a third party; (e) the recipients or categories of recipients of the personal data, if any; (f) where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49(1), reference to the appropriate or suitable safeguards and the means by which to obtain a copy of them or where they have been made available. 2. In addition to the information referred to in paragraph 1, the

includes, among others, the purposes of processing for which the personal data are intended as well as the legal basis for the processing; the period for which the personal data will be stored, or if that is just not possible, the criteria used to determine that period; and the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal.

3.5 National data protection laws

Although regulations do not require implementation, the Italian legal system had already developed certain data protection rules that do not implement, derogate or modify the GDPR, but that strengthen the protection afforded by it. Subsection 3.5.1 explores these rules. Furthermore, the GDPR allows for certain national choices and derogation. In 2018, the UK parliament enacted the Data Protection Act 2018 (hereafter: DPA 2018),[150] which develops the GDPR and, in certain cases, derogates from it. Subsection 3.5.2 outlines the relevant content of the DPA 2018.

3.5.1 Italy

Italian scholars have argued that the principles of the Oviedo Convention constitute the basis for the legal regime on the treatment of genetic data and for the interpretation of Italian legislation on the matter.[151]

The Directive 95/46/CE was implemented in Italy in 1996. [152] The implementation rules are now contained in the Italian Data Protection Code of 2003 (hereafter D.P.C),[153] which reorganised the whole area of data protection

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controller shall, at the time when personal data are obtained, provide the data subject with the following further information necessary to ensure fair and transparent processing: (a) the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period; (b) the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability; (c) where the processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;
(d) the right to lodge a complaint with a supervisory authority (e) whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, as well as whether the data subject is obliged to provide the personal data and of the possible consequences of failure to provide such data; (f) the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject(…)"

150 Available at <http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted> Last accessed 2 November 2019.

151 De Franco, 2007, 1351 with further references.

152 Legge n. 675 del 31 dicembre 1996: *Tutela delle persone e di altri soggetti rispetto al trattamento di dati personali*.

153 Decreto legislativo 30 giugno 2003 n. 196,, Code on the protection of personal data (*Codice in materia di protezione dei dati personali recante disposizioni per l'adeguamento dell'ordinamento*

law and collected all rules previously laid down in different statutes. After the GDPR entered into force, the Italian government issued the legislative decree n. 101 of 2018 to adjust the Italian legislation to the provision of the GDPR.[154] However, this adjustment did not repeal the D.P.C., which remains in force, albeit modified. In particular, Article 2-septies of the aforementioned decree details the conditions for the processing of genetic and health data, without further establishing any new limits to the validity of contracts on human tissue.

The regulation of the use of genetic data for scientific research under Italian law is somehow sui generis. The D.P.C. delegated the tasks and prerogatives for the regulation of the use of genetic data to the Italian Data Protection Authority (*Garante per la protezione dei dati personali*). According to Article 90 par. 1 D.P.C., "(t)he processing of genetic data carried out by any person, is allowed only in the cases of special authorization by the Data Protection Authority, once the Ministry of Health has been heard and has sought for that purpose the advice of the Superior Board of Health (*Consiglio Superiore della Sanità*) (…)."[155]

From the wording of Article 90 D.P.C. it can be deduced that the genetic data authorization is applicable to public and private subjects. In fact, Article 90 D.P.C. indicates that the processing of genetic data *by any person* is only allowed in cases of special authorization. Furthermore, the D.P.C. provides for a strengthened protection to genetic data in comparison to other types of health data. While as a general rule, health data can be processed after obtaining the consent of the person, the processing of genetic data requires the existence of a special authorization by the Data Protection Authority, which must seek the advice of the Ministry of Health and indirectly, the Superior Board of Health. The advices of the Ministry and the Board are not binding.[156]

The Italian Data Protection Authority issued therefore the general authorization for the processing of genetic data (Authorization n. 8/2016, hereafter, Genetic Data Authorization).[157] This authorization explicitly refers to principles included in supranational sources like the Oviedo Convention (Articles 10, 11 and 12), the Universal Declaration on the Human Genome and Human Rights (Articles 2, 5

nazionale alregolamento (UE) n. 2016/679 del Parlamento europeo e del Consiglio, del 27 aprile 2016, relativo alla protezione delle persone fisiche con riguardo al trattamento dei dati personali, nonche' alla libera circolazione di tali dati e che abroga la direttiva 95/46/CE).

[154] Decreto legislativo 10 agosto 2018, n. 101

[155] The translation is mine, the original reads as following: "*Il trattamento dei dati genetici da chiunque effettuato è consentito nei soli casi previsti da apposita autorizzazione rilasciata dal Garante sentito il Ministro della salute, che acquisisce, a tal fine, il parere del Consiglio superiore di sanità*."

[156] De Franco, 2007, p. 1354.

[157] Autorizzazione generale al trattamento dei dati genetici (Autorizzazione n. 8/2016).

and 6),[158] the CFREU (Article 21), the Directive 2004/23/CE (Article 14), and the International Declaration on Human Genetic Data[159] (Article 10) among others.

-List of definitions under the Genetic Data Authorization

The D.P.C. does not contain a definition of genetic data. However, Article 1 of the Genetic Data Authorization includes a list of definitions, whereby also the term genetic data is defined. For the purposes of the Genetic Data Authorization, genetic data is "(t)he result of a genetic test or any other kind of information that, independently of its typology, identifies the genotypic characteristics of an individual that are transmissible within a group of persons tied by kinship."[160] This Authorization also defines the term 'biological sample' as "(…) each sample of biological material from which the characteristic genetic data of an individual can be extracted."[161] Other terms defined in the Authorization are: genetic test, pharmacogenomics test, genetic screening, individual variability test, genetic counselling and genetic information.[162]

-Scope of application of the Genetic Data Authorization

Article 2 of the Genetic Data Authorization sets the scope of application by individualizing the subjects to whom the Authorization applies: a) health care professionals, and medical geneticists in particular, exclusively limited to data and activities necessary for the protection of the health of the person or a third party belonging to the same genetic line; b) public and private healthcare institutions, particularly the clinics specialized in medical genetics, exclusively limited to data and activities for the protection of the health of the person or a third party belonging to the same genetic line; c) medical genetics' laboratories; d) natural or legal persons, research institutions, associations or other public or private bodies with research purposes, exclusively limited to data and activities necessary to carry on research (including statistic research) for the protection of the health of the person, a third party, or the community in the medical biomedical and epidemiological fields and for the development of genetic testing technics; e) psychologists ; f) pharmacists and others. [163]

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[158] UNESCO, Universal Declaration on the Human Genome and Human Rights, 1997 (Hereafter Declaration on the Human Genome 1997).

[159] UN Educational, Scientific and Cultural Organisation (UNESCO), International Declaration on Human Genetic Data, 16 October 2003.

[160] Article 1 "*Ai fini della presente autorizzazione si intende per: a) dato genetico, il risultato di test genetici o ogni altra informazione che, indipendentemente dalla tipologia, identifica le caratteristiche genotipiche di un individuo trasmissibili nell'ambito di un gruppo di persone legate da vincoli di parentela*."

[161] Article 1 "(…) *b) campione biologico, ogni campione di materiale biologico da cui possono essere estratti dati genetici caratteristici di un individuo*."

[162] See Article 1 Genetic Data Authorization.

[163] Article 2: "(…) a) *agli esercenti le professioni sanitarie, in particolare ai genetisti medici, limitatamente ai dati e alle operazioni indispensabili per esclusive finalità di tutela della salute dell'interessato o di un terzo appartenente alla stessa linea genetica dell'interessato; b) agli*

-Rules on the use of genetic data

The specific rules on the use of genetic data contained in the Genetic Data Authorization do not differ substantially from the principles and rules laid down in the Data Protection Code for the use of personal data in general. According to this Authorization, the processing of non-anonymous genetic data and the use of non-anonymous human biological samples is only allowed if the goals of the research cannot be achieved with the processing of anonymous data or human biological samples or non-genetic personal data (Article 3.1). This rule corresponds to the principle of necessity laid down in Article 3 D. P. C. Moreover, the Authorization n. 8/2016 requires the preparation of a research project that includes the necessary measures to guarantee the confidentiality of the information (Article 4.2).

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organismi sanitari pubblici e privati, in particolare alle strutture cliniche di genetica medica, limitatamente ai dati e alle operazioni indispensabili per esclusive finalità di tutela della salute dell'interessato o di un terzo appartenente alla stessa linea genetica dell'interessato; c) a laboratori di genetica medica, limitatamente alle operazioni indispensabili rispetto a dati, parimenti indispensabili, destinati ad essere trattati per esclusive finalità di prevenzione e di diagnosi genetica nei confronti dell'interessato, o destinati ad essere utilizzati ad esclusivi fini di svolgimento delle indagini difensive o per far valere o difendere un diritto anche da parte di un terzo in sede giudiziaria o, ad esclusivi fini di ricongiungimento familiare, per l'accertamento della sussistenza di vincoli di consanguineità di cittadini di Stati non appartenenti all'Unione europea, apolidi e rifugiati; d) alle persone fisiche o giuridiche, agli enti o agli istituti di ricerca, alle associazioni e agli altri organismi pubblici e privati aventi finalità di ricerca, limitatamente ai dati e alle operazioni indispensabili per esclusivi scopi di ricerca scientifica, anche statistica, finalizzata alla tutela della salute dell'interessato, di terzi o della collettività in campo medico, biomedico ed epidemiologico, nell'ambito delle attività di pertinenza della genetica medica, nonché per scopi di ricerca scientifica volti a sviluppare le tecniche di analisi genetica; e) agli psicologi, ai consulenti tecnici e ai loro assistenti, nell'ambito di interventi pluridisciplinari di consulenza genetica, limitatamente ai dati e alle operazioni indispensabili per esclusive finalità di consulenza nei confronti dell'interessato o dei suoi familiari; f) ai farmacisti, limitatamente ai dati e alle operazioni indispensabili per esclusive finalità di adempimento agli obblighi derivanti da un rapporto di fornitura di farmaci all'interessato; g) ai difensori, anche a mezzo di sostituti, consulenti tecnici e investigatori privati autorizzati, limitatamente alle operazioni e ai dati indispensabili per esclusive finalità di svolgimento di investigazioni difensive di cui alla legge 7 dicembre 2000 n. 397; è altresì rilasciata per far valere o difendere un diritto anche da parte di un terzo- in sede giudiziaria, sempre che il diritto sia di rango almeno pari a quello dell'interessato e i dati siano trattati esclusivamente per tali finalità e per il periodo strettamente necessario al loro perseguimento; h) agli organismi di mediazione pubblici e privati limitatamente alle operazioni e ai dati indispensabili per esclusive finalità di espletamento delle attività inerenti all'esercizio della mediazione finalizzata alla conciliazione delle controversie civili e commerciali ai sensi del d.lg. 4 marzo 2010, n. 28 e successive modifiche e integrazioni, in conformità alla legge e nel rispetto, per gli organismi privati, delle prescrizioni dell'autorizzazione generale n. 5 al trattamento dei dati sensibili da parte di diverse categorie di titolari e, per gli organismi pubblici, del provvedimento del Garante del 21 aprile 2011 che individua i tipi di dati e di operazioni eseguibili in relazione alla finalità di rilevante interesse pubblico di cui all'art. 71, comma 1, lett. b) del Codic. i) agli organismi internazionali ritenuti idonei dal Ministero degli affari esteri e alle rappresentanze diplomatiche o consolari per il rilascio delle certificazioni (allo stato disciplinate dall'art. 52 d.lg. 3 febbraio 2011, n. 71) ad esclusivi fini di ricongiungimento familiare e limitatamente ai casi in cui l'interessato non possa documentare in modo certo i suoi vincoli di consanguineità mediante certificati o attestazioni rilasciati da *competenti autorità straniere, in ragione della mancanza di un'autorità riconosciuta o comunque quando sussistano fondati dubbi sulla autenticità della predetta documentazione*."

According to the Genetic Data Authorization the use of personal information (from the moment of the collection) must be residual, i.e. it is necessary to at least pseudonomyse the data (for example via the assignment of codes) at the earliest possible stage of the research (Article 4.2). Genetic data can only be processed and human biological samples can only be used for appropriate and effective scientific purposes. However, it is necessary to take into account first other research modalities and the possible use of non-genetic information to achieve the same purposes. Once it has been established that the use of genetic data and human biological samples are necessary to achieve the research goals, only the pertinent data and samples can be used (Article 4.2). This Authorization also prescribes that the appropriate safeguards should be taken in order to guarantee the custody and safety of the samples and the genetic data (Article 4.3).

Moreover, besides the general rules on consent contained in Articles 23 and 26 of the D.P.C., Article 6 of the Genetic Data Authorization prescribes that genetic data and human biological samples can only be used for the purposes of the authorization when the person had previously expressed her written consent.[164] The consent is only valid if the person is free from any kind of conditioning or coercion and is revocable at any time. If the person revokes the consent to the treatment of genetic data for research purposes, the biological sample that contains the data must be destroyed if it was collected for those purposes, unless the sample cannot be linked (from the beginning or after the treatment) to an identified or identifiable person.

-Other authorizations

Another relevant authorization for the use of genetic data and human biological samples in research is the general authorization for the processing of personal data for the purposes of scientific research (Authorization n. 9/2016).[165] This Authorization contains similar rules for what concerns the processing of personal data and the use of human biological samples.

These two authorizations bear relevance for the validity of the contracts on human biological material because they limit the lawful use of the samples and data associated to them.

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[164] "*In conformità a quanto previsto dagli artt. 23 e 26 del Codice, i dati genetici possono essere trattati e i campioni biologici utilizzati soltanto per gli scopi indicati nella presente autorizzazione e rispetto ai quali la persona abbia manifestato previamente e per iscritto il proprio consenso informato. In conformità all'art. 23 del Codice, il consenso resta valido solo se l'interessato è libero da ogni condizionamento o coercizione e resta revocabile liberamente in ogni momento. Nel caso in cui l'interessato revochi il consenso al trattamento dei dati per scopi di ricerca, è distrutto anche il campione biologico sempre che sia stato prelevato per tali scopi, salvo che, in origine o a seguito di trattamento, il campione non possa più essere riferito ad una persona identificata o identificabile* (…)"

[165] Autorizzazione generale al trattamento dei dati personali effettuato per scopi di ricerca (Autorizzazione n.9/2014).

3.5.2 England & Wales

In 2018, the UK parliament enacted the Data Protection Act 2018 (hereafter: DPA 2018),[166] which derogates from the Data Protection Act 1998.[167] Interestingly, before the DPA 2018 was enacted, the UK information commissioner already stated: "We will be members of the EU in 2018 and therefore it would be expected and quite normal for us to opt into the GDPR and then look later at how best we might be able to help British business with data protection while maintaining high levels of protection for members of the public."[168]

According to the explanatory notes to the DPA 2018, "Regulations do not normally require implementation as they are directly applicable as a result of Article 288 of the Treaty on the Functioning of the European Union ("TFEU"). In Case 39/72 Commission v Italy [1973] ECR 101 the court held that Italy was wrong to duplicate the provisions of EU regulations in domestic law."[169] For this reason, the DPA 2018 does not copy the provisions of the GDPR, but only refers to it when necessary to exercise derogations from the GDPR, when possible, or to extend the same protection afforded by the GDPR to areas not covered by its scope of application.

This section will only refer to the provisions of the DPA 2018 insofar as they may be relevant to the validity of contracts on human tissue. Particularly relevant is section 10, subsection (2) of the DPA 2018,[170] which provides that the processing under Article 9.2 literal (j) GDPR is only permitted by UK law if it meets certain conditions included in Part 1 of Schedule 1 of the DPA 2018. Article 9.2 literal (j) GDPR establishes an exception to the general prohibition of processing genetic data (included in article 9.1 GDPR). According to the former provision, processing of genetic data is allowed, when "necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject."

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[166] Available at: <http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted> last accessed 2 November 2019.

[168] https://ico.org.uk/about-the-ico/news-and-events/blog-how-the-ico-will-be-supporting-the-implementation-of-the-gdpr/. Last accessed 2 November 2019.

[169] Available at <http://www.legislation.gov.uk/ukpga/2018/12/notes/division/2/index.htm> last accessed 2 November 2019

[170] (2) The processing meets the requirement in point (b), (h), (i) or (j) of Article 9(2) of the GDPR for authorisation by, or a basis in, the law of the United Kingdom or a part of the United Kingdom only if it meets a condition in Part 1 of Schedule 1.

The conditions that the processing of genetic data must meet in order to be permitted by UK law are laid down in Schedule 1, part 1 Paragraph 4 of the DPA 2018 are that research: (a) is necessary for archiving purposes, scientific or historical research purposes or statistical purposes; (b) is carried out in accordance with Article 89(1) of the GDPR (as supplemented by section 19); and (c) is in the public interest.

According to Article 89(1) GDPR, "(…) processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner."

The aforementioned provision of the GDPR is complemented by section 19 DPA 2018, which establishes additional safeguards for the processing of sensitive data (including genetic data). According to section 19, Paragraph 2 the processing of personal data that is necessary for scientific or historical research purposes does not meet the requirement in Article 89(1) if it is likely to cause substantial damage or substantial distress to the data subject. Additionally, paragraph 3 of the same section indicates that: "(s)uch processing does not satisfy that requirement if the processing is carried out for the purposes of measures or decisions with respect to a particular data subject, unless the purposes for which the processing is necessary include the purposes of approved medical research."

Finally, based on the wording of Article 89(2) GDPR,[171] paragraph 27 Part 6 of Schedule 2 DPA 2018 establishes derogations from the rights referred to in Article 15(1-3), 16, 18(1) and 21(1) GDPR. These rights include:

1) The right of confirmation of processing, access to data and safeguards for third country transfers included within the more general right of access by the data subject (Article 15(1-3) GDPR); 2) The right to rectification (Article 16 GDPR); 3) The right to restriction of processing (Article 18 GDPR); and 4) the right to object (Article 21(1) GDPR).

[171] Article 89 GDPR "2. Where personal data are processed for scientific or historical research purposes or statistical purposes, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18 and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

According to paragraph 27 Part 6 of Schedule 2 DPA 2018, the aforementioned listed GDPR provisions "do not apply to personal data processed for—(a) scientific or historical research purposes, or (b) statistical purposes, to the extent that the application of those provisions would prevent or seriously impair the achievement of the purposes in question."

The following section will firstly, identify the limits to the validity of contracts stemming from data protection laws, and secondly, determine the differences between the different national laws.

3.6 Concluding remarks

This chapter has so far described three different data protection systems: the system stemming from the GDPR, and the Italian and the English regimes, which have embedded, further developed, or derogated from the GDPR.

This section identifies the possible limits to the validity of contracts on human biological samples stemming from these three different systems and provides some comparative conclusions. The limits deduced from the GDPR are: limits stemming from GDPR principles; limits stemming from the purpose limitation principle; limits stemming from the prohibition of processing genetic and health data; and limits stemming from informational duties.

- Limits stemming from GDPR principles

The GDPR may impose direct and indirect limits to the validity of contracts on human biological samples. A contract on human biological samples that involves the processing of personal data is bound to the principles of the GDPR, which were already embodied in the Directive 95/46/CE. According to Article 5(1) GDPR, these principles are: lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation and integrity and confidentiality. These principles do not apply to anonymous information. The notion of anonymous information includes data that do not relate to an identified or identifiable individual and anonymised data when the subject is no longer identifiable. Pseudonymised data are not excluded from the application of the GDPR principles (Recital 26 GDPR).

-Limits stemming from the purpose limitation principle

Particularly relevant for the determination of the limits to the validity of contracts on human biological samples is the purpose limitation principle (Article 5(1)b). It prescribes that further processing of data for archiving purposes in the public interest, or scientific purposes shall, in accordance with the safeguards included in Article 89(1) (e.g. pseudonymisation measures), not be considered to be incompatible with the initial purposes to which the data

were originally collected. The following example illustrates how the GDPR purpose limitation principle could constitute the ground for questioning the validity of contracts that involve the further processing of data for purposes that are incompatible with the initial ones: X (the first and original transferor of the sample) concludes a contract with Y (a university) for the purpose of using her sample in scientific research with no commercial purposes. After Y has concluded the research on X's sample, Y concludes a contract with Z (a pharmaceutical company) for the transfer of X's original sample for research with commercial purposes. Since Z's further processing of data does not aim directly at achieving purposes in the scientific or public interest, but aims at the obtention of commercial benefits, the purpose of the contract between Y and Z should not be considered as compatible with the initial purposes.

-Limits stemming from the prohibition of processing genetic and health data

Furthermore, with certain exceptions, the GDPR prohibits the processing of special categories of personal data (Article 9.1), including genetic and health data. The exceptions to this prohibition (Article 9.2) include the cases when explicit consent of the data subject is given to the processing of genetic data for one or more purposes, and the cases in which processing is necessary for scientific research purposes or statistical purposes. Arguably, a contract involving the processing of genetic or health data that does not fall within one of the exceptions of Article 9.2 GDPR may be declared invalid because of its contrariety to mandatory law.

-Limits stemming from the requirements of consent

Article 7 GDPR prescribes the conditions for consent for the processing of personal data. Among other conditions, according to Article 7.2, if the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters. Therefore, the question arises whether a requirement for the validity of a contract for the removal and use of a human biological sample in research should consist in asking for two separate types of consent: one consent for the removal of the sample and one for the processing of the data associated to the sample. Moreover, one could argue that a contract that does not allow for the withdrawal of consent at any time may be considered invalid on the grounds of contrariety to the GDPR (Article 7).

-Limits stemming from informational duties

Finally, Article 13 GDPR prescribes the information that needs to be provided by the controller (the first recipient of the sample) to the data subject (the first transferor of the sample), namely the purposes of processing for which the personal data are intended as well as the legal basis for the processing; the

period for which the personal data will be stored, or if that is just not possible, the criteria used to determine that period; and the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal. One may argue that Article 13 GDPR prescribes mandatory pre-contractual and contractual duties of information. Arguably, a failure to fulfil these duties by the first recipient of the samples might entail the invalidity of the contract.

The relevant limits applicable under Italian law are: limits stemming from the contrariety to mandatory law; limits stemming from the interpretation of the Oviedo Convention; and limits stemming directly from the Genetic data Authorization. In England the limits stem directly from the DPA 2018.

-Limits stemming from the conflict with mandatory law

In Italy, the conflict with any mandatory rule makes a contract invalid (see Part 3 Chapter CHAPTER 5 Contracts on human tissue in the light of general private law norms on the invalidity of contracts). Therefore, the analysis of the validity of a contract on human biological samples must take into account the mandatory rules laid down in all national sources of data protection law and the GDPR. Furthermore, all Italian rules on data protection law, including the Authorizations, and the GDPR integrate the contract:[172] they contribute to determine the effects of contracts on human tissue. Indeed, Article 1374 C.C on the integration of the contract prescribes that "(t)he contract binds the parties, not only to the content of the contract itself, but also to the consequences derived from the law, or in the absence of law, from customs and equity".[173] Therefore, for example, a recipient of a human biological sample has to take the appropriate safeguards in order to guarantee the custody and safety of the samples and the genetic data, even if the contract does not explicitly mention this obligation.

-Limits stemming from the interpretation of the Oviedo Convention

Additionally, Italian commentators have argued that the data protection rules incorporated in the Oviedo Convention[174] constitute the basis for the interpretation of national legislation on the matter. This argument seems to be confirmed by the fact that the Genetic Data Authorization explicitly refers to Articles 10, 11, and 12 of the Oviedo Convention, in addition to other international and supranational data protection documents i.e. the International

[172] I use the term "integration of the contract" as a literal translation of the Italian term "*integrazione del contratto"*, which refers to the inclusion of rules, in the contract, that were not agreed by the parties, but that are nonetheless part of its content. See Article 1374 C.C.
[173] The translation is mine, the original reads as following: "*Il contratto obbliga le parti non solo a quanto è nel medesimo espresso, ma anche a tutte le conseguenze che ne derivano secondo la legge, o, in mancanza, secondo gli usi e l'equità*."
[174] See section 3.5.1.

Declaration on the Human Genome and Human Rights (Articles 2, 5 and 6), the International Declaration on Human Genetic Data (Article 10) and the CFREU (Article 21).

-Limits stemming directly from the Genetic Data Authorization

Similarly to the provision of the GDPR (Recital 156), the Genetic Data Authorization prescribes that the use of non-anonymous data is only allowed if the goals of the research cannot be achieved with the processing of anonymous genetic data. Furthermore, the Genetic Data Authorization requires that the use of genetic data and human biological samples is only allowed if the person has expressed her written consent (Article 6). The GDPR, on the contrary, does not demand the necessity of the written consent. One may argue that in Italy, the contract for the use of human tissue and its data is a formal contract (*contratto solenne*)[175] because the consent must be expressed in writing.

Both the GDPR (Article 7) and the Genetic Data Authorization (Article 6) allow for consent to be withdrawn at any time. However, the effect of withdrawing consent under the Genetic Data Authorization is the destruction of the sample, unless the sample cannot be linked to an identified or identifiable person. Arguably, a contractual provision that precludes the donor of a human biological sample to withdraw her consent cannot be considered valid, because it clashes with the rules of Article 7 of the GDPR and Article 6 of the Genetic Data Authorization.

-Limits stemming from the DPA 2018

In the case of England & Wales, the structure of the DPA 2018 and its different entangled provisions with further normative references to other legal instruments, make it difficult to extract the relevant provisions that may limit the validity of contracts on human tissue.

However, from the analysis of the provisions of the DPA 2018 two main conclusions can be derived:

Firstly, the DPA 2018 does not allow the processing of genetic data for scientific purposes when such processing is likely to cause substantial distress to the data subject. This prohibition constitutes a limit to the validity of contracts on human tissue. A contract that involves the transfer of human tissue, and the processing of genetic data associated to it, is not valid, if such processing causes distress to the data subject. The determination of whether or not distress may be caused to

[175] A formal contract (*contratto solenne*) under Italian law is a contract that requires a formality (e.g. written form) for its valid conclusión. On the matter see: Dizionario Giuridico Broccardi, contratto. Available at: <https://www.brocardi.it/dizionario/1690.html>. Last visited: 2 November 2019.

the data subject will always depend on the analysis of the particular contract at hand.

Secondly, based on the provisions of the GDPR that allow for derogations, the DPA 2018 restricts the application of certain rights of the data subject, when such rights may trump the achievement of the scientific purpose. These rights include the right to access, the right to rectification, the right to restriction of processing, and the right to object. Based on the DPA 2018 and the GDPR, a contract for the transfer and use of human tissue may legally limit these rights insofar as the use of the tissue has scientific or other purposes recognized under the GDPR. In any other circumstances, such rights may not be validly restricted.

Part 3

ITALY

4

Chapter 4

Contracts on human tissue in the multi-level system of sources of law

PART 3 ITALY

CHAPTER 4 Contracts on human tissue in the multi-level system of sources of law

4.1 Overview of the relevant sources of law

The validity of contracts on human tissue under Italian law is regulated by a multiplicity of legal sources, whereby also international and European documents play an important role. The interaction between national, European and international sources creates a multi-level system of governance of contractual relationships in this field.[1]

In addition to the international and supranational legal sources analysed in Part 2 of this book, the validity of contracts on human tissue is regulated, at the national level, by the interplay of five types of norms:

(1) the general private law norms on the invalidity of contracts,
(2) the Civil Code provision regulating the validity of acts of disposition of the human body: Article 5 of the Italian Civil Code (*Codice Civile Italiano*,[2] hereafter, C.C.),
(3) the constitutional norms that are relevant for what concerns the acts of disposition of the human body: Articles 2, 3, 13, 23, 32 of the Italian Constitution (*Costituzione della Repubblica Italiana,*[3] thereafter, Cost.),
(4) Article 50[4] of the Italian Penal Code (*Codice Penale Italiano,*[5] hereafter, C.P.) on consent of the right holder as a general cause of exclusion of criminal responsibility (a norm which contributes to regulate the validity of contracts on the human body or its parts),
(5) Italian data protection law, as far as determinant for the (un)lawfulness of the use of human biological samples.

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[1] On the concept multi-level governance in private law see: Cafaggi, 2006.
[2] Codice Civile Italiano, R.D. 16 marzo 1942, n. 262 published in the extraordinary edition of the *Gazzetta Ufficiale della Repubblica Italiana*, n. 79, 4th of April 1942.
[3] Costituzione della Repubblica Italiana, published in the *Gazzetta Ufficiale della Repubblica italiana* n. 298, 27 December 1947. Online version at <http://www.governo.it/Governo/Costituzione/principi.html>
This book uses the English translation of the Italian Constitution by the Italian Senate available online at <https://www.senato.it/documenti/repository/istituzione/costituzione_inglese.pdf>
[4] Article 50 of the Italian Penal Code excludes the criminal responsibility for the harming or endangering of a right with the consent of the right holder.
[5] Codice Penale Italiano, R. D. 19 October 1930, n. 1398 published in the extraordinary edition of the *Gazzetta Ufficiale della Repubblica Italiana*, n. 251, 26th of October 1930.

4.2 Overview of the content of the following chapters

The interplay between the multiplicity of legal sources mentioned in the previous section is intricate. For purposes of clarity, the aforementioned sources will be addressed in the following order:

Firstly, Chapter 5 will address the general private law norms on the invalidity of contracts. Secondly, Chapter 6 will discuss the constitutional legal sources and their horizontal effect on private relationships. The constitutional sources are addressed first because they set the values underlying the contemporary Italian legal system and the goals to be achieved by interpreting and applying legislative norms, including the ones enacted before the Constitution came into force.[181] In fact, Article 50 C.P. and Article 5 C.C. were enacted in 1930 and 1942 respectively, followed later on by the Italian Constitution in 1947. Thus, after the entry into force of the Constitution, Italian scholars and judges faced the problem of coordinating the provisions of Article 5 C.C. and Article 50 C.P. with the new constitutional principles.[182] The results of this coordination exercise will be outlined in Chapters 7 and 8.

Thirdly, Chapter 7 will discuss Article 5 C.C. for what concerns its legislative history, original regulatory aims, scope of application, and constitutional interpretation.

Fourthly, Chapter 8 will discuss Article 50 C.P. in those aspects that are important for the validity of contracts on human tissue. Particularly, the notion of consent included in Art 50 C.P. will be addressed because it has direct consequences on the legal relationship between donor and recipient(s) of human tissue.

Fifthly, Chapter 9 will address the prohibition of financial gain from the human body and its parts. This prohibition can be deduced from European and international sources on human rights (See Part 2 Chapter 2), and the national legislation on transplants.

Sixthly, Chapter 10 analyses, in particular, the validity of contracts between the first transferor and the first recipient for profit**.**

Chapter 11 will address some contractual examples and problems from the contract practice on human tissue.

Finally, Chapter 12 presents some preliminary remarks.

[181] Alpa & Ansaldo, 2013, p. 365.
[182] Romboli, 1988, p. 227.

5

Chapter 5

Contracts on human tissue in the light of general private law norms on the invalidity of contracts

CHAPTER 5 Contracts on human tissue in the light of general private law norms on the invalidity of contracts

5.1 Overview

This chapter provides an overview of the notion of invalidity of contracts under Italian law, which may impact the validity of contracts on human tissue. As it will become apparent in the development of this chapter, the notion of invalidity provides a framework for the analysis of the relation between the validity of contracts on human tissue and: a) mandatory norms of international and supranational law sources (e.g. the GDPR); b) fundamental right enshrined in both supranational and national laws.

In addition, the notion of invalidity bears relevance for the analysis of the legislation on the limits to the acts of disposition for the human body (Chapter 7), for the analysis of other relevant legal sources that complement the legal regime of the acts of disposition of the human body (Chapters 7 and 8), and for the assessment of the validity of specific contracts on human tissue (Chapters 10 and 11).

As a general rule, the contract law notion of invalidity (*invalidità*)[183] refers to the juridical irregularity *(irregolarità giuridica)* of the contract that leads to its definitive inefficacy (*inefficacia definitiva*).[184] A juridical irregularity is caused by the failure of the contract or one of its elements to comply with legal norms. The inefficacy of the contract can operate automatically, or can be the consequence of judicial enforcement.[185] The category of invalidity includes the notions of nullity (*nullità*),[186] annullability (*annullabilità*),[187] and rescindability *(rescindibilità*)[188] of the contract. In all these forms of invalidity, the contract presents a more or less severe juridical irregularity (*irregolarità giuridica* or *difetto giuridico*).[189] The most severe one is the nullity.

The following sections will explore these irregularities. Section 5.2 outlines the notion of nullity, section 5.3 addresses the concept of annullability and section 5.4 provides an overview of the concept of rescindability. Section 5.5 concludes with some remarks on the validity of contracts on human tissue under general private law.

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[183] For an overview of the notion of invalidity see Camardi, 2016.
[184] Bianca, 1999, p. 573; Cian & Trabucchi, 2014, p. 1552.
[185] Bianca, 1999, p. 573.
[186] Article 1418 C.C.
[187] Articles 1425-1440 C.C.
[188] Articles 1447-1452 C.C.
[189] Bianca, 1999, p. 574; Zatti & Colussi, 2003, p. 465.

5.2 Nullity of the contract

The nullity of the contract is the most severe form of invalidity.[190] It is the consequence of the negative assessment of the contract because of the definitive absence of one of its constitutive elements,[191] or because of its illegality or social harmfulness.[192] According to Article 1418 C.C.,[193] the contract is void:

-When it is contrary to mandatory norms[194] (unless the law provides otherwise);

-In the absence of one of the constitutive elements of the contracts (that is the requirements indicated by Article 1325 C.C.: the agreement,[195] the cause,[196] the object[197] and the form[198]);

-When the cause of the contract, or the common motives of the parties in the cases indicated by Article 1345 C.C., are illegal;

-If the object of the contract is impossible, illegal, undetermined or indeterminable (Article 1346 C.C.);

-In the other cases indicated by the law.[199]

5.2.1 The constitutive elements of the contract: the agreement and the object

According to Article 1325 C.C., the constitutive elements of the contract are: the agreement (*accordo*) of the parties, the object (*oggetto*), the ground or cause (*causa*), and the form when it is required by the law in order to avoid the nullity of the contract.

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190 For a general work on the nullity of the contract see Di Marzio, 2008.
191 Bianca, 1999, p. 576; Zatti and Colussi, 2003, p. 465.
192 Ibid.
193 The original text in italian reads as following: "Il contratto è nullo quando è contrario a norme imperative, salvo che la legge disponga diversamente. Producono nullità del contratto la mancanza di uno dei requisiti indicati dall'articolo 1325, l'illiceità della causa, l'illiceità dei motivi nel caso indicato dall'articolo 1345 e la mancanza nell'oggetto dei requisiti stabiliti dall'articolo 1346. Il contratto è altresì nullo negli altri casi stabiliti dalla legge".
194 The mandatory nature of a legislative provision must be deduced from the public interest that the norm aims at protecting. On this see Cian & Trabucchi, 2014, p. 1552.
195 For case law on nullity of the contracts because of the absence of the agreement see e.g. Cass. Civ. 15 dicembre 1982, n. 6922; Cass. Civ. 29 settembre 2005, n. 19024.
196 For case law on nullity of contracts because of the absence of its cause see e.g. Cass. Civ. 14 febbraio 1984, n. 115; Cass. Civ. 27 luglio 1987 n. 6492; Cass. Civ. 15 giugno 1999 n. 5917; Cass. Civ. 8 maggio 2006 n 10490.
197 For case law on nullity of contracts because of the absence of its object see e.g. Cass. Civ. 19 gennaio 2006 n. 1040; Cass. Civ. 10 aprile 1996, n. 3329.
198 For case law on the nullity of contracts because of the absence of form see e.g. Cass. Sez. Un. Civili 17 settembre 2015 n. 18214. .
199 Special laws can indicate in which cases particular contracts are void.

The agreement of the parties refers to the reciprocal consent of the parties on the programme of the contract, i.e. the ways of creating, modifying, and extinguishing a legal patrimonial relationship (*rapporto giuridico patrimoniale*).[200]

In scholarly literature, the object of the contract has been defined in three different ways. Firstly, it has been sustained that the object of the contract are the performances due (*prestazioni dovute*).[201] Secondly, the object of the contract has also been defined as the material object upon which the contract will have effects.[202] For example, the object of a contract for the sale of a house is the house itself. Thirdly, it has been argued that the object of the contract is primarily its substantial content, in other words, what the parties have agreed on.[203] For example, the object of a sale is the transfer of the property or other real right in exchange of a price.[204] Some scholars adopt one, other scholars adopt two or more of these different definitions of the object.[205]

According to Article 1346 C.C.,[206] in order to be considered valid, the object of the contract should meet the following requirements: possibility (*possibilità*), legality (*liceità*), determination (*determinatezza*) or determinability (*determinabilità*). The contract lacks an object when the content of the contract is not determined, nor determinable.[207] While the object of the contract is its programme or substantial content,[208] the ground or cause of the contract has been defined as the practical reason of the contract, i.e. the objective socio-economic interests that the contract is meant to satisfy.[209]

5.2.2 The constitutive elements of the contract: the cause

The objective socio-economic interests pursued by the contract, which constitute its cause, must be differentiated from the motives (*motivi*) of the parties. The motives are the subjective interests that a party wants to satisfy with the contract but that are not part of its content.[210] For that reason, as a general rule the motives do not bear relevance for the creation of rights and obligations within the contract.[211] However, the law prescribes the nullity of the contract

[200] Bianca, G. Patti, S. Patti, 1995, p. 9; Camardi, 2016, p. 556.
[201] Torrente and Schlesinger, 2015, p. 592.
[202] Bianca, G. Patti, S. Patti, 1995, p. 563; Camardi, 2016, p. 589.
[203] Bianca, G. Patti, S. Patti, 1995, p. 562; Valle, 2012, p. 1485.
[204] Article 1470 C.C.
[205] See for example Camardi, 2016, p. 589.
[206] Article 1346 C.C.
[207] Torrente & Schlesinger, 2015, p. 593; Valle, 2012, p. 1488;
[208] Bianca, G. Patti, S. Patti, 1995, p. 166: "La causa si distingue rispetto all'oggetto del contratto. L'oggetto indica il programma, ossia il contenuto dell'accordo delle parti, mentre la causa indica l'interesse che tale programma è volto a soddisfare."
[209] Bianca, 1999, p. 419.
[210] Bianca, G. Patti, S. Patti, 1995, p. 499.
[211] Cian & Trabucchi, 2014, p. 1457; Valle, 2012, p. 1485.

when the motives of both parties are illegal (Article 1345 C.C).[212] Moreover, some provisions of the C.C. prescribe to take into account the intention of the parties for certain purposes (for example in interpreting the contract: Article 1362 C.C.[213]). Last but not least, according to the principle of good faith, the motives of one party should be considered and respected by the other, if this does not entail an extraordinary burden.[214]

Scholars have explained the requirement of the cause according to four different theories: the objective classical theory, the subjective classical theory, the theory of the cause as the typical socio-economic function, and the theory of the concrete cause (*causa concreta*).

The objective classical theory, stemming from 18th and 19th century French literature, focuses on the single contractual obligations, and recognizes the cause of each of them in their corresponding '*quid pro quo*' or counter-performance (*controprestazione*). Under this understanding, for example, the cause of the obligation of the seller is the price.[215] One of the weak points of this theory is provided by the donation: in the absence of an objective counter-performance of the donation, the cause cannot be identified in a corresponding '*quid pro quo*'. Already the 19th century French literature acknowledged that the cause of the donation was the liberality intent behind it,[216] but this meant a departure from the objective classical theory.

According to the subjective classical theory, the cause of the obligation is the purpose of the party, i.e. the motivation of consent.[217] This theory has not had much success in Italy, probably because it blurs the distinction between cause and motives, which seems to be fundamental for contemporary Italian scholars.

The theory of the typical socio-economic function of the contract understands the notion of cause as the typical and abstract socio-economic function of the contract.[218] Under this understanding, the cause is abstract because it refers to the abstractly considered function, as a constant aseptic regulation of interests that prescinds of the concrete context, the particular circumstances and the aims pursued by the parties. The cause implements the typical constantly repeated function of a given contractual type.[219] In the contract of sale, for example, the cause would be the exchange of a good for a price. This theory was traditionally

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[212] Cass. Civ. 31 ottobre 2014, n. 23158.
[213] According to Article 1346 C.C., when interpreting the contract it is necessary to go beyond the literal meaning of the wording of the contract and inquire about the common intention of the parties.
[214] Bianca, G. Patti, S. Patti, 1995, p. 500.
[215] Pothier, 1764, p. 12. For an overview of the objective classical theory see Bianca, 1999, p. 421.
[216] See for exampl the works of Domat.
[217] See the work of Capitant.
[218] Rolli, 2008, p. 67; Valle, 2012, p. 1479.
[219] Cian & Trabucchi, 2014, p. 1454; Rolli, 2008, p. 67 with further reference.

accepted by Italian scholars until the theory of the concrete cause was developed.[220] However, some modern Italian scholars still defend the theory of the abstract cause.[221]

According to the theory of the concrete cause, the cause is the concrete reason (*ragione concreta*), the practical function of the contract. Under this understanding, the notion of cause bears relevance insofar as one establishes the function that the single contract is meant to play in practice, as the individual-economic function.[222] According to this view, the cause and the contractual type do not coincide. It is not enough to verify if the contract is compatible with one of the abstract contractual models, but is necessary to find the practical meaning of the contractual operation with regards to the purposes that are part of it.[223] Therefore, by taking into account the concrete cause it is possible to assess the legal worthiness of the interests pursued by the contract. This theory is currently widely accepted by Italian scholars and courts.[224]

The cause is traditionally considered as one of the pillars that justify contractual autonomy.[225] The parties can freely regulate their interests by making use of either the contract types laid down in the Civil Code, or other, self-determined types of agreements not specifically foreseen by the legislation. Italian scholars differentiate between typical and atypical contracts. A typical contract (*contratto tipico* or *contratto nominato*) is a normative model, a legislatively determined contractual type (*tipo contrattuale*) for a recurrent economic operation,[226] i.e. a contract that has been explicitly regulated by law - for example, the contract of sale. An atypical contract (*contratto atipico or contratto innominato*) is a contract that does not fit in one of the legislatively determined contractual types.[227] Article 1322 C.C sets a general limit for the validity of atypical contracts. This provision states: "The parties can freely determine the content of the contract, within the limits imposed by the law (…). The parties can also conclude contracts that do not belong to the specifically regulated contractual types, provided that these contracts are aimed at achieving interests worthy of protection according to the legal system."[228]

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[220] Bianca, 1999, p. 423.
[221] Vallle, 2012, p. 1479.
[222] Cian and Trabucchi, 2014, p. 1454.
[223] Ferri, 1966, p. 249; Bessone, 1972, p. 207.
[224] Cass. Civ. 14 settembre 2012, n. 15449.; Cass. Civ. 29 maggio 2014, n. 12061. Galati, 2009 available at: http://www.treccani.it/diritto/approfondimenti/diritto_civile/1_Galati.html
[225] Bianca, G. Patti, S. Patti, 1995, p. 166. Camardi, 2016, p. 583.
[226] Bianca, 1999, p. 445.
[227] Bianca, 1999, p. 449; Bianca, G. Patti, S. Patti, 1995, p. 205.
[228] This is my personal translation. The original text in italian reads as following: "*Le* parti *possono liberamente determinare il contenuto del* contratto *nei limiti imposti dalla legge e dalle norme corporative. Le parti possono anche concludere contratti che non appartengano ai tipi aventi una disciplina particolare [*1323*], purché siano diretti a realizzare interessi meritevoli di tutela secondo l'ordinamento giuridico*".

The Italian Court of Cassation[229] has sustained that the objective concept of cause, i.e. the socio-economic function of the contract (that in the case of typical contracts is directly determined by the law), must be also present in the atypical contracts. In the case of atypical contracts, the cause should correspond to one of the abstract functions that the legal system considers worthy of protection. However, such function should not exclusively remain at the abstract level, but must be also present *in concreto*, in the actual contract brought into being (typical or atypical). The contract must have a concrete objective function that corresponds to one of the typically and abstractly determined functions. In the hypothesis of an atypical contract, the concrete cause created by the parties must fit into one of the functions worthy of protection.

The cause constitutes the foundation of the legal relevance of the contract: it is necessary that the agreement of the parties is justified by an appreciable objective interest behind it.[230] The cause is absent when an objective practical reason that justifies the contract is missing or when it pursues an interest deemed not to be worthy of protection according to the legal system.[231]

The cause of the contract has three different functions. Firstly, the cause serves as a criterion for the interpretation of the contract. The meaning of the agreement can be determined in relation to the interest(s) pursued. The cause allows the interpreter to clarify the meaning of the statements and behaviour of the parties, and to overcome potential incoherencies, ambiguities, or discrepancies within the contract.[232] Secondly, the cause works as a criterion for the qualification (*qualificazione*) of the contract. To legally qualify an act means to adscribe it to a legal category, or to a legally relevant category. To legally qualify a contract means to assess it according the contractual criteria, or in other words, to assign it to a certain contractual type or an appropriate mix of different contractual types (in the case of an atypical contract). Whilst the interpretation of the contracts is a factual assessment, the qualification of the contract is a legal assessment.[233] Thirdly, the cause works as a criterion for the adjustment (*adeguamento*) of the contract: the problem of the supervening events (e.g. impossibility to perform, breach of contract) that affect the

[229] C. Sez. U. 11 January 1973, n. 63. Rv 361835, in Foro it., 1973: *"(…) non ripudiandosi il concetto astratto ed obiettivo di causa come funzione economico-sociale del negozio, funzione posta direttamente dalla norma per ciascun contratto tipico e presente pur nei contratti atipici attraverso il limite della rispondenza concreta ad una delle funzioni astratte degne di tutela secondo l'ordinamento, devesi però ammettere che tale funzione non deve rimanere nel limite dell'astrattezza, ma deve essere presente anche nel contratto, pur tipico, concretamente posto in essere: quest'ultimo deve avere una funzione concreta, obiettiva, che corrisponda ad una delle funzioni tipicamente ed astrattamente determinate, come nell'ipotesi del contratto atipico la causa creata dalle parti deve rientrare in una delle funzioni degne di tutela."*

[230] Bianca, 1999, p. 429; Camardi, 2016, p. 583.

[231] Bianca, 1999, p. 581. For case law on the nullity of the contract because of the absence of the cause see for example Cass. Civ. 8 of May 2005 no. 10490; C 99/5917; C 92/12401.

[232] Bianca, 1999, p. 404 and 420.

[233] Bianca, 1999, p. 445.

development of the contractual relationship may find the appropriate solution if the objective socio-economic interest is taken into account.

The supranational and national legislation on data protection provides a few examples of cases whereby the notion of cause may play a role in the determination of the validity of contracts on human tissue. Both the GDPR and the Genetic Data Authorization allow for the further processing of genetic data without the initial consent of the first transferor of the tissue, when the processing of data is aimed at achieving effective scientific purposes.[234] Since the notion of cause aims at determining the objective interests behind a contract, one could argue that a contract on human tissue that does not have the consent of the first transferor because it is formally directed at achieving scientific research, but materially directed at other purposes, could be declared invalid on the grounds of illegality of the cause.

5.2.3 The illegality of the contract

The Italian Civil Code does not contain any provisions on the illegality of the contract as a whole. It only contains provisions on the illegality of constitutive elements of the contracts, which makes the contract null and void. The core norm in this regard is Article 1418 C.C.[235]

One of the grounds for the nullity of a contract under Article 1418 C.C. is the illegality of its cause, its object, or the common motives of the parties. Illegality means, according to Articles 1343 C.C., 1345 C.C. and 1346 C.C., contrariety to mandatory norms (*norme imperative*), public order (*ordine pubblico*) or good morals (*buon costume*). Article 1343 C.C. constitutes a manifestation of the need of protection of the fundamental values of society: a defence of collective values relating to a pacific and civilized life, economic and social progress, and a defence of the inalienable values of individual nature relating to the person's freedom, dignity, and security.

Mandatory norms

According to modern Italian literature,[236] the concept of mandatory norms under Article 1418 C.C. is different from the concept of mandatory norms under Article 1343 C.C. The notion of mandatory norms included in Article 1343 C.C. refers to prohibitive norms that prescribe insurmountable proscriptions, and are at the top of the hierarchy of values protected by the legal system: the fundamental ethical and legal principles of the legal system (*i principi giuridici ed etici fondamentali dell'ordinamento*).[237] The notion of mandatory norms embodied in

[234] See Part 2, section 3.4.
[235] On the content of Article 1418 C.C. see 5.2 above.
[236] Valle, 2012, p. 1581.
[237] Cass. Civ. 17 luglio 1981, n. 4414; Cass. Civ. 11 gennaio 1973, n. 63.

Article 1418 C.C. refers to norms that can be prohibitive, but also organisational *(ordinative)*, for the protection of public interests.[238]

The nullity of the contract derived from the contrariety to mandatory norms does not need to be explicitly stated in the mandatory norms themselves: it can also be implicitly deduced from the mere conflict between a contractual agreement and a mandatory norm.[239] Italian scholars differentiate between textual nullity (*nullità testuale*) and virtual nullity (*nullità virtuale*).[240] Textual nullity is the nullity explicitly prescribed by the norm. Virtual nullity is the nullity that derives from the mere contradiction between a contract (or a part of it) and a mandatory norm.

Supranational legal instruments do not explicitly prescribe the nullity of contracts governed by national laws. However, the category of virtual nullity allows mandatory norms at the supranational level to have an effect on the contract. When there is a contradiction between the content of a contract on human tissue and a supranational mandatory norm it would be theoretically possible to declare such contract as invalid. It is the case of the mandatory norms included in the GDPR. A contract that contradicts such norms could be declared invalid by an Italian judge using the category of virtual nullity.

Public order

The notion of public order[241] refers to the basic principles upon which the political and social order is founded.[242] A vast part of those principles can be found in the Italian Constitution. Particularly, the concept of public order includes the protection of fundamental rights.[243] In fact, the contracts that are prejudicial to the parties´ personality rights are affected by nullity when the limits of disposing of these rights are exceeded.[244]

Modern Italian scholars speak of different types of public order. Even though the terminology used by Italian scholars may differ among them, it is uncontroverted in literature that the scope of application of public order includes the economic,

[238] Valle, 2012, p. 1581.
[239] Cian and Trabucchi, 2014, p. 1553; Bianca, 1999, p. 582. For case law see: Cass. 7 Marzo 2001 n. 3272
[240] Valle, 2012, p. 1576.
[241] For Italian scholarly works on the notion of public order see, for example: Ferri, 1994, p. 441; Paladin, 1965, p.130. For case law on the notion of public order see, for example: Cass. Civ. 10 ottobre 2005, n. 20197; Cass. Civ. 5 luglio 1971, n. 2091.
[242] Bianca, 1999, p. 584; Ferri, 1994, p. 441; Paladin, 1965, p. 130
[243] Bianca, 1999, p. 584.
[244] Bianca, 1999, p. 584.

social and moral spheres.[245] A possible classification of the types of public order includes the following:[246]

-Public order of direction and economic structure (*ordine pubblico di direzione e struttura economica*);

-Personal and familiar public order (*ordine pubblico personale e familiare*) for the protection of the values of the person and the family;

-Political public order (*ordine pubblico politico*) for the protection of the state community;

-Public order of protection (*ordine pubblico di protezione*), which refers to the whole of principles and values for the protection of the interests of persons belonging to weak social-economic groups, e.g. consumers or workers.[247]

A contract on human tissue that is contrary to public order is illegal. In the same way as the cause of the contract may function as a way to bring down the mandatory norms at the supranational level, the notion of public order may function as a way to analyse the validity of a contract in relation to fundamental rights enshrined at the national[248] and supranational level.[249]

Good morals

Italian scholars have given different interpretations to the concept of good morals.[250] Francesco Ferrara was arguably the first Italian scholar that derived the notion of good morals from the one of social moral. Ferrara defined social moral as an unceasingly progressive social product, constituted by an array of ideas and sentiments that are the reflection of a community's conscience and are generally recognized by it.[251] Antonio de Ruggiero suggested some years after Ferrara, that good morals are a broad and elastic notion.[252] These ideas remained unchanged even after the entry into force of the Italian Civil Code of 1942. In fact, Italians scholars sustained that the social moral is a historically variable notion and good morals are represented by the principles underpinning

[245] Terlizzi, 2013, p. 86.
[246] Terlizzi, 2013, p. 86.
[247] Cian and Trabucchi, 2014, p. 1455.
[248] For the analysis of the relationship between constitutional principles, fundamental rights and the validity of the contract see Part 3 Chapter 6.
[249] On the relationship between fundamental rights enshrined in supranational law sources and the validity of contracts see Part 2 Chapter 2.6.
[250] On the different interpretations of the notion of good morals and its historical evolution see Terlizzi, 2013.
[251] Ferrara, 1914, p. 27.
[252] De Ruggiero, 1931, p. 278.

it.[253] According to this scholarly position, social moral is what is generally practiced by the majority of correct, honest people in a certain place and in a certain moment.[254] Some modern scholars still define good morals in similar terms. It has been argued, for example that good morals refer to the ethical principles that constitute the social moral[255], i.e. the set of rules that guides the majority of correct people, acting in good faith and with good principles, at a certain time and at a certain place. [256]

It has also been argued that the concept of good morals is part of the concept of social moral but does not deplete it. While social moral indicates the set of moral duties generally accepted in social relations, (e.g. the duties of correctness), good morals indicate the negative precepts of social honesty, i.e. the rules that impose to a person the duty to do not behave contrary to the common sense of honesty.[257] The acts contrary to the common sense of honesty do not only include the acts offensive to sexual dignity but also all the other acts that are condemned by social conscience at a specific historical moment.[258]

In any case, the aforementioned views on the concept of good morals have in common that it has an autonomous nature with respect to other concepts like public order or mandatory norms. The characterizing element of good morals is its tendency to function as an elastic[259] and general notion that allows the legal system to innovate without the need of many formal procedures.[260] The content of the notion of good morals is likely to change from a particular historical moment to another, and from one person to another.[261]

However, in the 1960s and 1970s, the autonomous concept of good morals was problematized by a part of the scholarly literature: the idea of good morals began to be understood as something similar and sometimes equivalent to the notion of public order. [262] It has been sustained that while contractual freedom has permeated 'new territories' e.g. commercial agreements for the use of the name, the acts of disposition of the human body and surrogacy agreements, also "new

[253] Messineo, 1944, p. 247. For a dissenting voice on the concept of good morals at the time see Trabucchi, 1959, p. 700-706. According to Trabucchi, the concept of good morals makes references to an idea of social moral that implies the Christian moral.
[254] Messineo, 1944, p. 247; D'Addino Serravalle, 1983, p. 157; Dogliotti, 1982, p. 78.
[255] Torrente and Schlesinger, 2015, p. 603.
[256] Torrente and Schlesinger, 2015, p. 603; Cian and Trabucchi, 2014, p. 1455. For case law on this understanding of good morals see e.g. Cass. Civ. 21 aprile 2010 n. 9441.
[257] Bianca, 1999, p. 585.
[258] Cass. 17 July 1981, n. 4414. For examples of the application of the 'contrariety to good morals' clause in contracts not relating to sexual conducts see Cass. Civ. 23 maggio 1985 n. 2081; Cass. 27 maggio 1971, n. 1574.
[259] Cian and Trabucchi, 2014, p. 1455.
[260] Romboli, 1988, p. 232.
[261] Pizzorusso, 1978, p. 104.
[262] Rescigno, 1966, p. 26; Roppo, 1977, p.168.

values"[263] like the principles of dignity and self-determination have emerged.[264] These two parallel processes led to a transformation of the concept of public order of protection into a 'philanthropic public order', characterized by the absence of a univocal meaning, and a changing behaviour depending on the types of goods and interests involved.[265] For this reason, the prevalent opinion sees that many of the hypotheses that were traditionally included under the notion of good morals are now being contained under the concept of public order. According to this opinion, public order includes all general principles (political, economic, and social) aimed at protecting the community life in a certain society in a specific time.[266] It appears that according to the now prevailing opinion in Italian scholarly literature, only the contracts contrary to human dignity could be considered as contrary to good morals.[267]

According to a minority opinion, the criteria for the assessment of the contrariety to public order differ from the criteria for the assessment of the contrariety to good morals: while the contrariety to public order refers to a contrariety to the foundations of the legal order, the contrariety to good morals indicates an opposition to social honesty.[268]

Moreover, some Italian scholars include the notions of public order and good morals within the broader notion of mandatory norms.[269] According to this view, public order is constituted by mandatory norms that are not explicitly included in ordinary legislative provisions but are implicitly recognized by the legislative system (e.g. in legislative codes and the Constitution). Along the same lines, good morals are also part of the notion of mandatory norms implicitly recognized by the legislative system that refer to the assessment of a person's behaviour in terms of morality and honesty.[270]

This book follows the now prevalent Italian scholarly opinion, according to which good morals only play a role when the contract is contrary to human dignity. However, this book still considers the distinction between public order and good morals relevant because an important difference between the contrariety to good morals and the contrariety to public order consists in that according to Article 2035 C.C, the contractual performances having a purpose contrary to good morals are null but the payments already made cannot be

[263] These values are new to the realm of contract law but not to the Italian legal system in general.
[264] Terlizzi, 2013, p. 87.
[265] Resta, 2006.
[266] Gazzoni, 2013, p. 810.
[267] Terlizzi, 2013, p. 90; Di Marzio, 2008, p. 389.
[268] Bianca, 1999, p. 585.
[269] Valle, 2012, p. 1581.
[270] Valle, 2012, p. 1582.

claimed back.[271] Therefore, if a contractual performance is 'only' contrary to public order, the payments made can be claimed back.[272]

Admitted the existence of a close link between the notion of good morals and human dignity, Italian judges could declare a contract on human tissue as invalid when contrary to human dignity.[273]

5.3 The annullability of the contract

The annullability of the contract is regulated in Articles 1425-1446 C.C. As a general rule, the annullability is a remedy for the protection of the interest of one contract party whose consent to the agreement was invalid because of her individual situation or because of particular circumstances.[274] The contract affected by annullability produces effects until a court declares its annulment (*annullamento*).[275]

The general grounds for the annullability of the contract are the party´s incapacity (Article 1425 C.C.) and the vices of the will (*vizio del volere*): mistake, duress or fraud (Article 1427 C.C.).

5.3.1 Incapacity

Italian private law distinguishes between legal incapacity (Article 1425 C.C.) and natural incapacity (Article 428 C.C.). A party may lack legal capacity for reasons of age or mental illness. Minors do not have legal capacity unless otherwise provided by legislation (Article 2 C.C.). If a mental illness is so serious that it makes a person incapable of taking care of her interests, the person can be declared interdicted (*interdetta*) or inabilitated (*inabilitata*) by a court (Articles 414 and 415 C.C.)

According to Article 1425 C.C. "(t)he contract is annullable if one of the parties was legally incapable of contracting. The contract is likewise annullable, under the conditions set by Article 428 C.C, when a person incapable of understanding and willing concluded it.[276]

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[271] Torrente & Schlesinger, 2015, p. 603.
[272] Bianca, 1999, p. 591: "(…) le prestazioni eseguite in tutto o in parte costituiscono un indebito oggettivo in quanto prive di titolo e devono essere restituite"
[273] On the different meanings of the notion of human dignity and its relationship with contracts on human tissue see Part 6 Chapter 22
[274] Bianca, 1999, p. 603; Trimarchi, 1975, p. 191.
[275] Bianca, 1999, p. 603
[276] The translation is mine, the original reads as following: "*Il contratto è annullabile se una delle parti era legalmente incapace di contrattare. È parimenti annullabile, quando ricorrono le condizioni stabilite dall'articolo 428, il contratto stipulato da persona incapace d'intendere o di volere*".

Article 428 C.C. states: "The acts made by a person who, albeit not declared interdicted, for any reason, even temporary, has been proven to have been incapable of understanding and willing at the moment of the making of the act, can be annulled upon request of that person (…) if they caused a serious disadvantage to the agent."[277] According to Italian case law, a person is incapable of understanding if she cannot realise the meaning of her own actions, and a person is incapable of willing if she lacks self-determination.[278]

5.3.2 Vices of the will

The vices of the will are a) mistake (Article 1428 et seq. C.C.), b) duress (Article 1434 et seq. C.C.) and c) fraud (Article 1439 et seq. C.C.).

Mistake

Mistake is the party's false representation of the contract or its terms. Italian scholars distinguish between vice-based mistake (*errore vizio* or *errore motivo*) and impediment-based mistake (*errore ostativo*).[279] The vice-based mistake refers to the formation of the party's will: without the mistake the party would not have entered into the contract. The obstacle-based mistake refers to the party's declarations: the party has correctly formed her will but it has been wrongly declared or expressed.[280] Italian literature also distinguishes between mistake concerning facts (*errore di fatto*) and mistake concerning the law (*errore di diritto*). While the former refers to the contractual elements or the external circumstances, the latter refers to the applicable legal norms.[281]

The mistake causes the annulment of the contract when it is essential (*essenziale*) and recognizable (*riconoscibile*) for the counterparty: Articles 1428, 1429 and 1431 C.C.

The requirement of the essentiality of the mistake refers to its objective relevance: a contract cannot be challenged only because a party incurred in a mistake but it is necessary that the mistake has an appreciable relevance with regards to the objectives of the contract.[282] According to Article 1429 C.C., a mistake is essential if it assumes for the party a decisive importance according to an objective assessment, i.e. when it refers to:

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[277] The translation is mine, the original reads as following: "Gli atti compiuti da persona che, sebbene non interdetta, si provi essere stata per qualsiasi causa, anche transitoria, incapace d'intendere o di volere al momento in cui gli atti sono stati compiuti, possono essere annullati su istanza della persona medesima o dei suoi eredi o aventi causa, se ne risulta un grave pregiudizio all'autore."

[278] For case law on this matter see Cass. Civ. 8 agosto 1997, n. 7344; Cass. Civ. 25 ottobre 1997, n. 10505; Cass. Civ. 26 maggio 2000, n. 6999; Cass. Civ. 13 dicembre 2011, n. 26729.

[282] Torrente & Schlesinger, 2015, p. 545.

(1) The nature of the contract (*error in negotio*). For example when a person thinks to conclude a contract of sale by instalments, while the contracts is in reality a leasing;
(2) The object of the contract (*error in corpore*). For example when a person believes to buy screws but she in reality is buying nails;
(3) The identity of the object of the performance or one of its qualities if this can be considered as determinant of consent (*error in substantia*). For example if a person thinks she is buying animal wool but in reality it is synthetic wool;
(4) The identity or the specific qualities of the counterparty if these are determinant of consent (*error in personam*).
(5) The applicable law if it has been the unique or main reason for the party to conclude the contract.

According to Article 1431 C.C., a mistake is recognizable if a normally diligent person could have noticed the mistake of the other party in relation to the content, the circumstances of the contract or the quality of the parties.[283]

At least two examples can be provided to understand the relationship between the legal category of mistake and the validity of contracts on human tissue. The first one is the lack of informed consent. A person that has transferred a tissue sample for the use of the data associated to it, without the appropriate informed consent, may argue that her will was not properly formed and seek the annullability of the contract. The second example is a mistake in the nature of the contract. A person that transferred a tissue sample thinking it was to be used in research on cancer, when the sample was, in reality, to be used in research on HIV.

Duress

According to Articles 1435 and 1436 C.C., duress is the violence or threat that forces a person to enter into an unwanted contract or to agree to a specific contractual content. It is a cause of annullability when it consists in either a serious threat of an unlawful wrong to the person or goods of the contract party or third parties, or a threat of exercising a right in order to obtain an unlawful advantage.

Duress is the most severe and socially frowned upon form of violation of freedom of contract. It is the result of the arbitrary and unjust imposition of a person's will on the contractual autonomy of a party. Duress constitutes a vice of

[283] Torrente & Schlesinger, 2015, p. 549. See also Cass. Civ. 12 novembre 1979, n. 5829.

the will when it is serious and unjust.[284] Duress is deemed unjust when the threat consists in an unlawful injury to a person or to his patrimony.[285]

According to Article 1435 C.C.[286] "(d)uress must be of such a nature that impresses a reasonable person and makes her fear of exposing herself or her goods to a remarkable and unjust wrong (…)". The seriousness of duress must be assessed *in concreto*, i.e. with regard to the specific circumstances of the case. On this issue, Article 1435 C.C. specifies that "(c)onsideration shall be given in this matter to the age, gender and conditions of the persons".

The parameter of a "reasonable person" is a criterion valid for normal situations, and indicates the suitability of the threat to influence the will of the contractual party. If the threat does not influence a reasonable person, then it cannot be said that the person's will has been affected by duress. The seriousness of the threat refers to the possibility of it taking actual place, and to the nature of the wrong threatened to be inflicted.[287]

Fraud

Fraud is any kind of deception that alters the contractual will of the victim. It is a cause of the annullability of the contract when it is decisive for the person's consent, i.e. when the deception induces the person to enter into a contract that she would not have concluded otherwise. This kind of fraud is referred to as vice-based fraud (*dolo vizio* or *causam dans*). Fraud causes the annullability of the contract when there has been an action from the counterparty aimed at deceiving the victim, and the victim has been effectively deceived.[288] The vice-based fraud must be differentiated from the incidental fraud (*dolo incidente* or *incidens*). The incidental fraud refers to a deception that is not determinant of consent, but influences the content of the contract, i.e. the person would in any case have entered into the contract but she would have done it under different terms or conditions. In any case, fraud constitutes a wrongdoing because it violates contractual freedom.

In a similar way as the category of mistake, the category of fraud may be used to seek the annullability of the contract, when the person was led to believe that her tissue was to be used for a different purpose than it was actually used for.

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[284] Bianca, 1999, p. 620. Torrente & Schlesinger, 2015, p. 553.
[285] Bianca, 1999, p. 620.
[286] The translation is mine, the original reads as following: "*La violenza deve essere di tal natura da fare impressione sopra una persona sensata e da farle temere di esporre sé o i suoi beni a un male ingiusto e notevole. Si ha riguardo, in questa materia, all'età, al sesso e alla condizione delle persone.*"
[287] Bianca, 1999, p. 620.
[288] Torrente & Schlensinger 2015, p. 551.

5.4 The rescindability of the contract

Rescindability (Article 1447 et seq. C.C.) is a form of invalidity of the contract for the protection of the party that concludes the contract under unequitable conditions because of a state of need or danger not caused by the actions of the counterparty.[289]

The state of need characterizes the general action of rescindability. This action requires also the profiting (*approfittamento*) of the other contractual party beyond half of the value of the counter-performance. Indeed, according to Article 1448 C.C., the contract is only rescindable if the disproportion exceeds the half of the value that the performance made or promised by the harmed party had at the time the contract was concluded.

The state of danger is characterized by the fact that the party concludes the contract because of the need (known by the counterparty) of saving himself/herself or others from a serious danger (Article 1447 C.C).[290]

5.5 Concluding remarks on the validity of contracts on human tissue under general private law

From the three different forms of invalidity – nullity, annullability and rescindability – the rescindability is arguably the one that finds less application to contracts on human tissue. It is difficult to imagine a scenario where a person concludes a contract on human tissue to save herself or others from a serious danger. In contrast, the other two forms of invalidity (annullability and nullity) bear special relevance for the assessment of the validity of contracts on human tissue. The annullability of a contract on human tissue may occur because of the incapacity of the transferor of the human tissue (e.g. minors) or because a vice of the will. In particular, the category of mistake might prove useful for the analysis of cases where the original transferor of the tissue made a mistake on the nature of the contract she was concluding, for example when the person believed she was concluding a contract for non-profit research on a particular disease and the contractual purpose was in reality the commercial exploitation of this research. The category of fraud might be relevant for the analysis of cases where the person was deceived to conclude a contract, for example when the person was made to believe to transfer human tissue for purely diagnostic purposes while in reality the material was to be used for obtaining a patent which would secure considerable financial gain for the patent holder.

[289] Bianca, 1999, p. 620 with further reference to Scalfi, 1991.
[290] A specific case on the matter of state of danger and marine rescue was decided by the Supreme Court the 7 of January 1925, n. 938.

The nullity of the contract is without doubt the most relevant form of invalidity for what concerns contracts on human tissue. While the nullity of such contracts on ground of absence of one constitutive element (the agreement, the cause, the object and the form) arguably only rarely comes into consideration, the opposite is true for what concerns the nullity on grounds of illegality. One may think of many possible examples of contracts on human tissue, whose objects or cause might be contrary to mandatory norms, public order or good morals, e.g. a contract for the transfer of human tissue with the purpose of carrying on eugenic practices. More generally, one could argue that a contract for the transfer of human tissue in exchange of valuable consideration is illegal because of the illegality of the cause or the object (making the human body as a source of financial gain).[291]

Mandatory norms, public order and good morals do not exclusively pertain to the realm of contract law, but are legal categories that make reference to constitutional principles or other basic principles of the political and social order (in the case of mandatory norms and public order) or to fundamental and constitutional rights, including human dignity (in the case of good morals). The following chapter identifies and describes the relevant constitutional framework for the acts of disposition of the human body.

[291] See Part 3 Chapter 9.

6

Chapter 6

The effect of constitutional norms on the validity of contracts on human tissue

CHAPTER 6 The effect of constitutional norms on the validity of contracts on human tissue

6.1 Overview

This chapter highlights the constitutional norms and rights relevant for the determination of a normative framework for the regulation of the acts of disposition of the human body and its parts. Such constitutional norms and fundamental rights may have a direct and an indirect effect on contracts on human tissue. In the previous chapter I provided a few examples of the indirect effect of fundamental rights through the application of general clauses of private law like good morals and public order. This chapter will analyse the horizontal effect of fundamental rights insofar as relevant for the validity of contracts on human tissue.

For this purpose, section 6.2 firstly describes the terminology used by the Italian Constitution and literature to refer to fundamental rights and fundamental principles (subsection 6.2.1), and analyses in particular the notion of human dignity (subsection 6.2.2). Secondly, section 6.3 assesses whether or not fundamental rights and constitutional principles have horizontal effect under Italian law. Thirdly, section 6.4 describes the principles that constitute the general constitutional framework that applies to the acts of disposition of the human body. Section 6.5 provides some concluding remarks on the effect of constitutional norms on the validity of contracts on human tissue.

6.2 Fundamental principles and fundamental rights

6.2.1 Preliminary remarks

Italian legislation and legal literature speak of '*diritti inviolabili*' (inviolable rights) to refer to the rights known as 'fundamental rights' in other legal systems. The Italian term '*diritto fondamentale*' is rarely found in Italian legislation. However, scholars use both expressions as synonyms.[292]

The Italian Constitution differentiates between fundamental principles (Articles 1 to 12 Cost.) and citizens' rights and duties (Articles 13 to 54 Cost.). Fundamental principles are the basis for the coexistence of different rights and constitute the cornerstone of the Italian constitutional system.[293] Fundamental rights are not only recognised in Articles 13 to 54 Cost.: perhaps the most important constitutional legal basis for the recognition of fundamental rights is Article 2 Cost.

[292] Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 325.
[293] Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 327, with further reference. Paladin, 1998, p. 561.

6.2.2 Human dignity and fundamental rights under the Italian Constitution

The Italian Constitution does not explicitly recognize human dignity as inviolable.[294] It only includes one explicit mention of the term 'human dignity' in Article 41[295], and only other two references to the concept of dignity can be found in Articles 3[296] and 36 Cost.[297] Italian scholars have sustained that from a systematic understanding of these articles it can be derived that the respect for the human person and the respect for human dignity are two perfectly equivalent expressions. In other words, the protection of the inviolability of the human person in the Italian Constitution is a synonym of the protection of the inviolability of human dignity.[298]

Moreover, a widespread view in Italian scholarly works deduces from Article 2 Cost. an implicit acknowledgment of the fundamental principle of human dignity[299] and the values underpinning it.[300] Article 2 Cost. states that "(t)he Republic recognises and guarantees the inviolable human rights, be it as an individual or in social groups expressing their personality, and it requests the performance of the unalterable duty to social, economic, and political solidarity."[301]

The prevalent Italian opinion considers human dignity as a fundamental principle or a supra-constitutional value and sees Article 2 as an expression of the core of fundamental rights represented by human dignity.[302]

Italian scholars have argued that Article 2 Cost. is of importance for at least three reasons.[303] Firstly, Article 2 Cost. recognizes and guarantees the inviolable rights of the person, which implies that the human person is at the top of the values of the Italian normative system. Secondly, Article 2 Cost. links together the human

294 Mattioni, 2011, p. 69
295 According to Article 41 Cost. human dignity is a limit to the private economic initiative. Cfr. Mattioni, 2011, p. 70.
296 According to Article 3 Cost. all citizens have equal social dignity.
297 According to Article 36 Cost. the retribution to the worker must be enough to guarantee a dignified existence.
298 Mattioni, 2011, p. 69;
299 Monaco, 2010, p. 46.
300 Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 327, with further reference.
301 "*La Repubblica riconosce e garantisce i diritti inviolabili dell'uomo, sia come singolo, sia nelle formazioni sociali ove si svolge la sua personalità, e richiede l'adempimento dei doveri inderogabili di solidarietà politica, economica e sociale." Costituzione della Repubblica Italiana, a cura del Consiglio di Ministri edito dal istituto poligrafico dello Stato*. The English translation is available at: https://www2.immigrazione.regione.toscana.it/sites/default/files/costituzione/Costituzioneitalianaversioneinglese.pdf . Last consulted: 3 December 2018. This source is used for all the following English translations of the Italian Constitution.
302 Monaco, 2010, p. 47; Ruggeri, 1991, p. 347; Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 327.
303 Scalisi, 1990, p. 35-36.

person and social groups. In the Italian constitutional system, social groups are instrumental in relation to the development of human personality. The legitimacy and the protection of social groups are subordinated to the respect of the existential needs of the human being. According to the Italian Constitution, it is not the human being that is instrumental to the social groups, but the social groups that are instrumental to the person and the values that the person represents. Therefore, the needs of social groups cannot take pre-eminence over the existential needs of the single human being. Thirdly, Art. 2 Cost. is important because it explicitly mentions the duties of political, economic and social solidarity.

Article 2 Cost. serves two different functions. On the one hand it works as a safeguard for the individual against the powers of the sovereign State. On the other hand, it grants inviolable rights within social groups and protects the free development of the individual's personality. As a consequence, the balancing of different fundamental rights should take the inviolability of personality into consideration.[304]

Article 2 Cost. has been the object of different interpretations arising from the debate of whether or not the Italian Constitution includes a closed list of fundamental rights or if it allows for the recognition of rights that have not been explicitly included therein. At first, the Italian Constitutional Court interpreted Article 2 Cost. restrictively by arguing that it only provides a summary of the rights guaranteed by the Constitution.[305] However, this view changed, and the Constitutional Court now sustains that Article 2 is a general clause that constitutes the foundation for the recognition of rights that are not explicitly included in the Constitution,[306] e.g. right to honour, right to respect for private life, right for reputation and right to a home.[307]

Among Italian scholars two positions can be identified on the interpretation of Article 2 Cost. According to the prevalent opinion, Article 2 Cost. allows considering some rights that are not included in the constitution as inviolable.[308] According to a minority opinion, only the rights that have been explicitly included in the Constitution can be deemed as inviolable because otherwise the judiciary would be granted with excessive discretionary powers.[309] This latter position has been criticized considering that Article 2 Cost. does not refer only to

[304] Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 327.
[305] Corte Cost. 4 maggio 1972 no. 77; Corte Cost. 10 ottobre 1979, no 125; Corte Cost. 22 dicembre 1980, no. 188.
[306] Corte Cost. 24 gennaio1994 n. 13.
[307] Corte Cost. 7 aprile 1988 no. 404.
[308] Barbera, 1975, p. 83; Morelli, 1999, p. 12-15. Cf. Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 331 with further references.
[309] Pace, 1989, p. 689. Cf. Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 332 with further references.

rights in a strict legal sense, but also to a set of values underpinning the rights therein included.[310]

The present book adheres to the prevalent opinion among Italian scholars:[311] it follows both the Italian Constitutional Court and the Italian Supreme Court (Court of Cassation: *Corte di cassazione*) and considers Article 2 Cost. as a general clause open to the evolution of the legal system, which constitutes the bases for the constitutional recognition of new emerging values.[312] This book also follows the view according to which the fundamental principle of human dignity is implicitly acknowledged in Article 2 Cost.

6.3 Horizontal effect of fundamental rights and constitutional principles

Italian scholars use the term 'horizontal effect' to refer to the effectiveness, protection,[313] relevance[314] or application of constitutional norms between private persons. The use of a specific terminology for the application of fundamental rights seems to be more common in academic literature than in case law. When referring to the concept of horizontal effect, Italian scholars use either the literal translation of this English term (*effetti orizzontali*),[315] the German term *Drittwirkung*[316] or its translation (*efficacia rispetto ai terzi*),[317] or they speak of the 'immediate effects' or 'direct applicability' of fundamental rights.[318] The reference to these terms is often made when fundamental rights are seen as limitations of other rights,[319] e.g. limitations of the freedom of contract.

Italian scholars and courts admit the application of fundamental rights through the interpretation of general clauses or open norms of private law,[320] but the use of the term 'indirect application' of fundamental rights is not widespread in Italy.[321] Some Italian scholars distinguish between direct application and application though general clauses, without speaking of 'indirect application'. Other authors use the terms 'combined' or 'coordinated' application of

[310] Modugno, 1995, p. 3. Cf. Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 332 with further references.
[311] Navaretta, 2004, p. 23. Alpa, 2002, p. 198.
[312] Cass. Civ. 7 febbraio 1996, n. 978. In the same line, the Constitutional Court in decision Corte Cost. 24 gennaio 1994, n. 13.
[313] Barile, 1994, p. 60; Bin & Pitruzzella, 2000, p. 480; Di Majo, 1982, p. 13-14. Cf. Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 340 with further references.
[314] Alpa, 2000, p. 521.
[315] Bin & Pitruzzella, 2000, p. 480.
[316] Alpa, 2000, p. 521-72; Barile, 1994, p. 60; Silvestri 1993, p. 485.
[317] Rescigno, 1982, p. 47.
[318] Alpa, 1995, p. 45.
[319] Morelli, 1997, p. 519.
[320] Cerri, 1982, p. 47.
[321] For very recent scholarly litarature on the horizontal effect of fundamental rights included in the CFREU see Libertini, 2019, p. 65.

constitutional principles together with the norms of civil law.[322] Apart from these terminological differences, substantively, both the direct and the indirect horizontal effect are recognised in Italian jurisprudence.[323]

Italian judges follow a case-by-case approach to grant the application of fundamental rights in the relation between private persons depending on the nature of the fundamental right involved and the private relationship and the way the right has been formulated by national or supranational sources of law.[324]

Italian courts have given horizontal application to several articles of the Constitution. For contract law matters, the following articles bear particular relevance: Article 2 in relation to the good faith clause;[325] Article 3 in relation to the general principle of equality and general contract law;[326] and Article 32, particularly in relation to labour contracts.[327]

Italian scholars have identified general criteria to grant horizontal application to fundamental rights. A first criterion is based on the nature of the fundamental right: if the fundamental right belongs to the private sphere it should be given application between individuals.[328] A second criterion is based on the nature of the private relationship.[329] Finally, in contract law, another criterion has been proposed: if there is a gross disparity between the parties because of an asymmetric relationship, then fundamental rights must be applicable to the contractual relationship, for example in the cases of standard or collective contracts.[330]

6.4 General constitutional framework for the regulation of acts of disposition of the human body

The Italian Constitution does not include a specific norm meant to regulate the acts of disposition of the human body and its parts. However, scholars and judges have used several principles embodied in constitutional norms to create a general normative framework that applies to the acts of disposition of the human

[322] Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 341
[323] Colombi Ciacchi, 2014, p. 113.
[324] Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 342
[325] Cass. Civ. 4 marzo 2003, n. 3185; Cass. Civ. 24 settembre 1999, n. 10511; Cass. Civ. 13 settembre 2005, no. 18128.
[326] Corte Cost. 1 aprile 1992, n. 149; Corte Cost. 3 febbraio 1994, n. 19.
[327] Examples of the first cases on the horizontal application of constitutional norms to labour contracts are: Trib. Firenze, 23 March 1948 (1949) n. 18; Trib. Genova, 25 May 1974 (1975), n. 54; Cass. 10 August 1953, no. 2696 (1953). Cf. Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010.
[328] Barile, 1999, p. 135-52; Bin & Pitruzzella, 2000, p. 480-484; Maiello, 1997, p. 20.
[329] For example, a testator may chose the recipient if his/her estate based on the affiliation to a certain religion. The same behaviour of an employer could constitute illegitimate discrimination. Cf. Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 345, fn. 139.
[330] Mak, Sanchez Galera, Wünsch, Ramos, Kraus, 2010, p. 345.

body.[331] This general normative framework includes Articles 2,[332] 3,[333] 13,[334]23,[335] and 32[336] Cost. Italian courts, following the aforementioned case-by-case approach, could grant application to the fundamental rights embodied in these articles in contracts for the transfer and use of human tissue.

According to the prevalent opinion in Italian legal literature, two main principles lie at the basis of this general normative framework: the personalistic principle and the pluralistic principle.[337]

[331] Veronesi, 2011, p. 140.

[332] "The Republic recognises and guarantees the inviolable human rights, be it as an individual or in social groups expressing their personality, and it requests the performance of the unalterable duty to social, economic, and political solidarity." ("*La Repubblica riconosce e garantisce i diritti inviolabili dell'uomo, sia come singolo, sia nelle formazioni sociali ove si svolge la sua personalità, e richiede l'adempimento dei doveri inderogabili di solidarietà politica, economica e sociale*").

[333] "All citizens have equal social dignity and are equal before the law, without distinction of sex, race, language, religion, political opinion, personal and social conditions. It is the duty of the Republic to remove those obstacles of an economic or social nature which constrain the freedom and equality of citizens, thereby impeding the full development of the human person and the effective participation of all workers in the political, economic and social organization of the country." ("*Tutti i cittadini hanno pari dignità sociale e sono eguali davanti alla legge, senza distinzione di sesso, di razza, di lingua, di religione, di opinioni politiche, di condizioni personali e sociali. È compito della Repubblica rimuovere gli ostacoli di ordine economico e sociale, che, limitando di fatto la libertà e l'eguaglianza dei cittadini, impediscono il pieno sviluppo della persona umana e l'effettiva partecipazione di tutti i lavoratori all'organizzazione politica, economica e sociale del Paese.*")

[334] "Personal liberty is inviolable. No one may be detained, inspected, or searched nor otherwise subjected to any restriction of personal liberty except by order of the Judiciary stating a reason and only in such cases and in such manner as provided by the law. In exceptional circumstances and under such conditions of necessity and urgency as shall conclusively be defined by the law, the police may take provisional measures that shall be referred within 48 hours to the Judiciary for validation and which, in default of such validation in the following 48 hours, shall be revoked and considered null and void. Any act of physical and moral violence against a person subjected to restriction of personal liberty shall be punished. The law shall establish the maximum duration of preventive detention." ("*La libertà personale è inviolabile. Non è ammessa forma alcuna di detenzione, d'ispezione o perquisizione personale, né qualsiasi altra restrizione della libertà personale, se non per atto motivato dell'Autorità giudiziaria e nei soli casi e modi previsti dalla legge. In casi eccezionali di necessità ed urgenza, indicati tassativamente dalla legge, l'autorità di Pubblica sicurezza può adottare provvedimenti provvisori, che devono essere comunicati entro quarantotto ore all'Autorità giudiziaria e, se questa non li convalida nelle successive quarantotto ore, si intendono revocati e restano privi di ogni effetto. È punita ogni violenza fisica e morale sulle persone comunque sottoposte a restrizioni di libertà. La legge stabilisce i limiti massimi della carcerazione preventiva*."

[335] "No obligation of a personal or financial nature may be imposed on any person except by law." ("*Nessuna prestazione personale o patrimoniale può essere imposta se non in base alla legge.")*

[336] "The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent. No one may be obliged to undergo any health treatment except under the provisions of the law. The law may not under any circumstances violate the limits imposed by respect for the human person." ("*La Repubblica tutela la salute come fondamentale diritto dell'individuo e interesse della collettività, e garantisce cure gratuite agli indigenti. Nessuno può essere obbligato a un determinato trattamento sanitario se non per disposizione di legge. La legge non può in nessun caso violare i limiti imposti dal rispetto della persona umana*".)

[337] Veronesi, 2011, p. 140-143 with further references.

The personalistic principle is a fundamental principle of the Italian Constitution. This principle, enunciated in Articles 2 and 3 Cost., places the protection of the human person at the top of the pyramid of legal values[338] and puts at the centre of society the interests and rights of the individuals, in opposition to the 18th century vision that considered first the interests of the State and protected the interests of the person only in function of the objectives of the State.[339]

According to the pluralistic principle, values do not hold an immutable and universal truth applicable to everyone.[340] This principle manifests itself in different contexts and assumes various forms recognized by Italian scholars: social pluralism (Article 2 Cost.); political pluralism (Article 49 Cost.); religious pluralism (Articles 7, 8, and 19 Cost.); institutional pluralism (e.g. Articles 5, and 18 Cost.); and ethical pluralism.[341] A pluralistic Constitution intends to create an open system of values, where one's specific values cannot unjustifiably exclude the ones of the others.[342]

According to Veronesi, the interplay between the personalistic and the pluralistic principle gives legitimacy to the societal objective of finding the maximum extension possible for the individual's capacity of self-determination, provided that the interests and rights of others are taken into account and adequately balanced with the ones of the person herself.[343]

Italian scholars[344] distinguish between the active and passive aspects of the right to personal inviolability enshrined in Article 2, 13 and 32 Cost. On the 'active' aspect of the right to personal inviolability the Italian Constitutional Court sustained:[345] "the constitutional value of the inviolability of the person must be construed as a freedom entailing the power of the person to dispose of her body"[346]. The 'passive' aspect includes the right of the person to prevent interferences on her body that are not constitutionally justified, particularly by Articles 13[347] and 32 Cost., even in the cases in which the violation of the physical integrity may contribute to the physical or psychological wellbeing of the person (e.g. chirurgical operation for the treatment of a given disease).[348]

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[338] Scalisi, 1990, p. 34.
[339] Amato, 1967, p. 304; Occhiocupo, 1988, p. 16.
[340] Veronesi, 2011, p. 144
[341] Casonato, 2006, p. 14; Chieffi, 2000, p. XVI with further references.
[342] Veronesi, 2011, p. 144. Cfr. Zagrebelsky, 1988, p. 26.
[343] Veronesi, 2011, p. 145.
[344] Romboli, 1991, p. 17
[345] Corte Cost. 9 ottobre 1990, n. 471.
[346] No official translation is available. This is my personal translation. The original text in italian reads as following: "il valore costituzionale della inviolabilità della persona"(...) va costruito come libertà nella quale va postulata la sfera di esplicazione del potere della persona di disporre del proprio corpo."
[347] On the connection between Article 13 and the right to life and physical integrity see Corte Cost. 9 luglio 1996, n. 238.
[348] Romboli, 1988, p. 239; Campanelli 2005, p. 22.

Articles 13 and 32 Cost., and Article 2 Cost. to a minor extent, provide for the constitutional basis for the right (and its limits) of the individual to dispose of her body, but both answer to two different rationales.[349]

Article 13 Cost. has been object of two different interpretations. According to a strict interpretation,[350] the scope of Article 13 includes only the protection of the person against physical coercion. On the contrary, a broad interpretation includes within the right to personal freedom not only the inviolability of the human body on the grounds of physical duress, but also the person's moral freedom and social dignity when she is object of moral or psychological pressure.[351] This latter view has been also supported by a case law line of the constitutional Court,[352] and is considered as the prevalent interpretation under modern Italian law. However, under both interpretations, the object of Article 13 is the human body. Personal freedom, therefore, manifest itself in the right of the individual to decide about her body, without external interferences willing to hamper or force the legitimate use of her right.[353]

Article 32 Cost. is the cornerstone of any Italian legal debate on the individual's health and constitutes one of the most significant personalistic traits of the Italian Cost.[354] It must be read in the context of the protection of the human person and therefore in accordance with Articles 2 and 3 Cost.[355]

Article 32 Cost. includes physical integrity within its scope of application[356] and protects the right to health in its two dimensions: as a personal right and as a collective interest. Under the former dimension, it implies that both public and private powers should refrain from influencing the ways in which the individual (when capable) manages her own health and body.[357] Article 32 Cost. does not provide a definition of the notion of health,[358] but the modern understanding of it is defined as: "(…) complete physical, mental and social well-being and not merely the absence of disease or infirmity.[359] Therefore, in order to protect the

[349] Veronesi, 2001, p. 152.
[350] Pace, 1992, p. 178.
[351] Barbera, 1967, p. 12; Barile, 1984, p. 111.
[352] Corte Cost. 3 luglio 1956 n. 11; Corte Cost. 8 marzo 1962, n. 20; Corte Cost. 24 maggio 1963, n. 74; Corte Cost. 24 novembre 1994, n. 419; Corte Cost. 19 maggio 1997, n. 144..
[353] Filipetta, 2006, p. 560; Pace, 1992, p. 295; Romboli, 1988, p. 239.
[354] For a detailed view on the relation between the right to health and constitutional principles see: Ferrara, 2010, p. 3.
[355] D'Arrigo, 2001, p. 1009.
[356] Luciani, 1980, p. 562; Mazzoni, 2008, p. 120; Comandé, 2014, p. 42.
[357] Comandé, 2014, p. 39. For the interpretation of article 32 Cost. see, for example, the following decisions of the Italian Constitutional Court: Corte Cost. 12 luglio 1979, n. 88; Corte Cost. 14 luglio 1986, n. 184; Corte Cost. 2 giugno 1994, n. 218; Corte Cost. 30 giugno 2003, n. 233.
[358] Dell'Utri, 2012, p. 441.
[359] Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

fundamental right to health, it is necessary to take into consideration the conditions, personal opinions and ways of being of the right holder, while at the same time respecting the pluralist and personalistic principles.[360]

Italian scholars have debated about the position assumed by the writers of the Italian constitution regarding the disposability or non-disposability of physical integrity. Some[361] have argued that there is a constitutionally protected right to dispose of the human body: the disposability should be considered the general rule that may be excepted under specific circumstances. For example, according to Comandé, "(…) the unitary notions of health (not only in relation to physical integrity but also including mental health) and of the human being have made it possible to consider severed parts of a body as mere objects upon which one's own rights could be exercised. Rather, the transformation means that body parts are now considered objects upon which liberty is exercised."[362] Some others maintained that the basic rule is the non-disposability of the physical integrity, with the exceptions explicitly stated by legislation.[363]

None of the aforementioned positions finds explicit support in the Italian Constitution, but both of them can be convincingly argued for.[364] Both the protection of physical integrity (Article 32 Cost.) and the freedom of deciding on one´s human body (Article 13 Cost.) are constitutionally protected values and fundamental human rights.

Problems arise when both rights and values conflict with each other and must be concretely balanced against each other, when a private act pursuing the realization of one of them, collides with the other.[365] In cases of conflict between physical integrity and the freedom of deciding on one´s body, the assessment of which of these values should outweigh the other cannot be done in abstract, but should be done on a case by case basis.[366]

Furthermore, some scholars have argued that the freedom of deciding about one's health encompasses not only the negative aspect (e.g. refusing medical treatments) but also the active aspect. Under this active aspect, the protection of health would entail also the freedom of deciding about one's physical being.[367] Under this understanding, a person's freedom of disposing of her body should be considered a manifestation of the broader freedom of disposing of her being.[368]

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[360] Veronesi, 2011, p. 153.
[361] Cherubini, 1978, p. 82.
[362] Comandé, 2014, p. 42.
[363] Salazar, 1983, p. 53.
[364] Alpa & Ansaldo, 2013, p. 363; Romboli, 1991, p. 566.
[365] Romboli, 1988, p. 240.
[366] Romboli, 1988, p. 241.
[367] D'Arrigo, 2001, p. 1009.
[368] D'Arrigo, 2001, p. 1009.

The acts of disposition of the human body may either have effect exclusively on the private sphere of the individual disposing of her body, or may also produce their effects on other persons or the society as a whole. Some[369] have argued that the freedom of deciding on one's body should prevail over the protection of physical integrity when the effects of the acts of disposition fall exclusively within the private sphere of the individual disposing of her body. According to this position, if the personalistic principle is one of the pillars on which the legal system stands, the State should guarantee the development of human personality, and freedom of deciding on one's body should prevail over the protection of physical integrity.[370] However, the balancing of these two values should be done on a case by case basis if the acts of disposition of the human body involve third parties, for example when the execution of the act entails the participation of other persons (e.g. medical staff), or when the act of disposal is meant to benefit another person (e.g. a transplant).

6.5 Concluding remarks on the effect of constitutional norms on the validity of contracts on human tissue

The constitutional framework described at the beginning of the previous subsection (6.4) serves as a compass to determine and balance the relevant principles, rights and liberties that are relevant for the cases involving the right to dispose of one's own body. Furthermore, fundamental rights that are part of this constitutional framework could be applied directly or indirectly by Italian judges in cases involving contracts on human tissue. In this regard, the application of fundamental rights through the interpretation of open norms or general clauses of private law creates a virtuous circle whereby the content of these open norms is filled with constitutional principles and fundamental rights.

In particular, the fundamental principle and supra-constitutional value of human dignity, embodied in Article 2 Cost. constitutes the basis for the constitutional recognition of new emerging values and may play a significant role in the assessment of the validity of contracts on human tissue. Specifically, human dignity could serve as a criterion for assessing the illegality of the cause and object of the contract.

In this book, the constitutional sources were addressed first because they set the values underlying the contemporary Italian legal system and the goals to be achieved by interpreting and applying legislative norms, including the ones enacted before the Constitution came into force. In fact, before the Italian Constitution entered into force, the acts of disposition of the human body and its parts were only regulated by Article 50 C.P. and Article 5 C.C. The following Chapters (7 and 8) will provide an overview of the original regulatory aims,

[369] Mantovani, 1980, p. 244; Pezzini, 1983, p. 38.
[370] Romboli, 1988, p. 242.

scope of application and modern constitutional interpretation of Article 5 C.C. and Article 50 C.P.

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Chapter 7

Contracts on human tissue and Article 5 of the Italian Civil Code

CHAPTER 7 Contracts on human tissue and Article 5 of the Italian Civil Code

7.1 Overview

The legal regime for the disposition of the human body and its parts has been traditionally based on Article 5 C.C. which reads: "The acts of disposition of the own body are prohibited when they cause a permanent reduction of the person's physical integrity, or when they are otherwise contrary to law, public order or good morals."[371]

This chapter's aim is twofold. Firstly, it aims at providing a comprehensive overview of the legislative history of Article 5 C.C., and its historical background and regulatory objectives (section 7.2). Secondly, it aims at analysing Article's 5 C.C. limits to the acts of disposition of the human body and its parts, i.e. the permanent reduction of the person's physical integrity, public order and good morals (sections 7.3 and 7.4). Section 7.5 provides a number of conclusions.

With "permanent reduction of the person's physical integrity", the legislator of 1942 meant an injury that renders the person unsuitable for the accomplishment of her duties towards the family or the State. This understanding was firstly expressed by the Italian Supreme Court (*Corte di cassazione,* Court of Cassation) in a 1934 case[372] that constitutes the *occasio legis* for Article 5 C.C.: the *Vornonoff* case.[373]

7.2 Legislative history and regulatory aims

7.2.1 The Vornonoff case

In 1931, a young student in Naples sold one of his testicles to a rich and famous Italian-Brazilian lord, who, seduced by the promise of having a reinvigorated virility, decided to have it implanted (Vornonoff transplant).[374] The case reached the criminal courts on the issue of the criminal liability of the physicians that had explanted the sex gland from the young student. The prosecution argued that the doctors had committed the crime of grievous bodily harm (*lesioni personali aggravate*) without a cause of justification.[375] According to the prosecution, the consent of the right holder (a cause of justification that could have excluded the

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[371] This is my personal translation. The original text in italian reads as following: "Gli atti di disposizione del proprio corpo sono vietati quando cagionino una diminuzione permanente della integrità fisica, o quando siano altrimenti contrari alla legge, all'ordine pubblico o al buon costume."

[372] Cass. Pen., 31 gennaio 1934. *Corte di Cassazione del Regno*.

[373] Italian scholars have not given any names to this case. I have named it "The *Vornonoff* case".

[374] The method for the implantation of the testicles was developed by Serge Vornonoff, hence the name of the transplant.

[375] This cause of justification is included in Article 50. C.P. On the relation between Article 5 C.C. and Article 50 C.P- see Chapter 8.

criminal liability) was irrelevant because the young student did not have any right of disposition of the organs of his body.[376]

The arguments raised by the defence were based on the importance of medical experimentation, and the absurdity of trying to impose limits to scientific research.[377]

The case was first decided by the courts of Napoli and finally reached the Italian Court of Cassation in 1934. All the decisions were in favour of the physicians. The court of first instance absolved the physicians considering that the removal of a testicle does not alter the ordinary functionality of the reproductive organ. The court of appeal reached the same conclusion on the basis that the consent of the right holder constitutes a cause of justification. In fact, the court of appeal considered that a testicle is a part of the human body that can be the object of a transfer because such a transfer does not go against the laws of the State (the transferor can still perform his duties towards the State), nature (the transferor can still procreate) or morality (the transferor is making a sacrifice for a noble end).[378] The decision of the Court of Cassation was also in favour of the physicians. On the issue of the validity of the acts of disposition of the human body the Court of Cassation decided:

"As a rule, all rights should be considered of a alienable nature, in the sense that they involve, without distinctions, a private juridical act of disposition[379] (…)" "(…) (T)his principle can find an obstacle if the private juridical act is in contrast (…) with prohibitions expressly stated by law, or with good morals or public order. The consent of the right holder is a private juridical act of disposition (…) that has the power of excluding a criminal offense only when it is intended to authorize a damage to the body that does not make the individual physically and socially unsuitable for the fulfilment of his duties towards the family or the State. In the cases of lesions to the personal integrity that cause a damage of a certain relevance to the body, but that do not surpass the abovementioned limit, the social moral considers consent as licit only insofar as it contributes to an end of particular social relevance; and the benefit for the health of another person is, per se, an end of particular social relevance. It is not relevant whether the person who gave his consent received a pecuniary compensation".[380]

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[376] For a summary of this case see Dell'Utri, 2012, p. 416.
[377] Dell'Utri, 2012, p. 417: "(…) *poichè la pretesa di <<porre vincoli alla ricerca scientifica>>, o di <<imprigionare il fervore della sperimentazione che studia, saggia, e tenta>>, è quanto <<di più assurdo si possa concepire>> risolvendosi, infine, nella <<più antigiuridica delle pretese>>.*"
[378] Cfr. Romboli, 1988, p. 227.
[379] The Italian term is "*negozio giuridico*", which means act of private autonomy recognised by law.
[380] This is my personal translation. The original text in italian reads the following: "*Di regola tutti i diritti debbono ritenersi disponibili nel senso che comportano, senza distinzione, qualunque negozio giuridico dispositivo (…)""(…) Tale principio può trovare ostacolo nel fatto che il negozio*

7.2.2 Article 5 C.C: historical background and regulatory objectives

Article 5 C.C. came into force with the enactment of the Civil Code of 1942. The previous Italian Civil Code of 1865, as other European Civil Codes of that time (such as the French and German ones), devoted one of its books to the "persons", but did not contain any rules on acts of dispositions of the human body or its parts.[381]

The Italian legislator of 1942 had the *Vornonoff* case in mind when it drafted Article 5 C.C.[382] In fact, in the report of the Royal Commission accompanying the final draft of the Italian Civil Code (*Relazione della Commissione Reale al Progetto definitivo*) it can be read: "A norm was therefore considered appropriate that allows such private juridical acts of disposition when they are not contrary to law or good morals. Special consideration was given to the cases where a person's body undergoes scientific experiments or chirurgical operations (very frequent today, for example, those for blood transfusion). If such agreements were plainly deemed void, this would unfairly deprive of compensation the person who undergoes similar experiments or operations agreeing on it in advance."[383]

The *occasio legis* and the preparatory works of the Italian Civil Code arguably demonstrate with a certain degree of reliability that Article 5 C.C. was enacted to fill an existing legislative gap and to regulate the acts of disposition of the human body or its parts that involve or benefit third parties.[384] This is for example the case when an act of disposition of the human body necessitates the participation

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giuridico *sia in contrasto con divieti espressamente posti dalla legge ovvero con il buon costume o con l'ordine pubblico. Il consenso dell'avente diritto è un negozio giuridico dispositivo (…) che ha efficacia di escludere il reato solo quando sia rivolto ad autorizzare un danno al corpo che non renda l'individuo fisicamente e socialmente inidoneo all'adempimento dei suoi doveri in rapporto alla famiglia e allo Stato. Nei casi di lesioni alla integrità personale, che importano un pregiudizio di una certa rilevanza al corpo, ma che non oltrepassi il limite suddetto, la morale sociale valuta come lecito il consenso solo a condizione che concorra uno scopo di particolare valore sociale; ed il vantaggio alla salute di un'altra persona è di per se, uno scopo di particolare valore sociale. Non ha rilevanza il fatto che il consenziente abbia ricevuto un compenso pecuniario*". Cass. Pen., 31.1.1934. *Corte di Cassazione del Regno*. Available online at <http://www.jstor.org/stable/23128661?seq=1#page_scan_tab_contents> last accessed 13 of December 2019.

[381] According to Rodotà, 2006, p. 74, the Civil Code of 1865 "completely ignored the physicality" of the person, except for some limited hints to the person's birth and death.

[382] Rodotà, 2011, p. 53.

[383] This is my personal translation. The original text in italian reads as following: "*Si è pertanto ritenuta adeguata una norma che dichiari tali disposizioni permesse quando non siano contrarie alla legge o alla morale. Si è avuto riguardo specialmente ai casi in cui taluno sottoponga il suo corpo ad esperimenti scientifici, ad operazione chirurgiche (molto frequenti oggi, ad es., quelle per la trasfusione del sangue). Se si dicesse senz'altro che tali convenzioni sono nulle si verrebbe ingiustamente a privare del compenso colui che si sia sottoposto a simili esperimenti od operazioni pattuendolo preventivamente*". Relazione della Commissione Reale, p. 33. Cited in Resta, 2011, p. 807. Fn. 11.

[384] Romboli, 1988, p. 228.

of medical staff, or when the ultimate purpose of the act is the transplant of a human body part.

On the one hand, Article 5 C.C. intended to generally declare the lawfulness of the acts of disposition of the own body,[385] which implied the validity of acts for the transfer of a part, a product or a function of the human body, even in exchange of consideration.[386] The relevant part of the report of the Ministry of Justice accompanying the final draft of the Italian Civil Code (*Relazione del Guardasigilli al Progetto definitivo)* reads: "Article 5 solves the problem of the lawfulness of the acts of disposal of the own body. Taking inspiration from indispensable moral and social needs, the new code prohibits such acts not only when they are contrary to law, public order or good morals, but also when they cause a permanent reduction of the physical integrity".[387]

On the other hand, Article 5 C.C. was meant to set general limits to private autonomy to protect interests that under the fascist perspective of the time,[388] were considered of a "higher level", e.g. the productive and reproductive capacity of the individual.[389] This is the reason why the limit of the "permanent reduction of the person's physical integrity" established by Article 5 C.C. constituted the first and most important criterion to determine the validity of the acts of disposition of the human body. All the other limits set by Article 5 C.C. (acts "otherwise contrary to law, public order or good morals") assumed a residual importance under the regulatory aim of the time.[390]

Physical integrity was not understood as an intrinsic value to be protected *per se*, but it was conceived as something instrumental to the achievement of the essential State´s goals and activities. The person was seen as a father or mother, to provide for the family and to "produce" kids, as a worker that contributes to the socio-economic progress of the nation, and as a soldier that protects the country from foreigners.[391] The report of the Ministry of Justice accompanying the final draft of the Italian Civil Code (*Relazione del Guardasigilli al Progetto definitivo)* reads on this matter: "The norm that prohibits the abuse of a right is

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[385] Alpa and Ansaldo, 2013, p. 360; C. Perlingieri, 2010, p. 266.
[386] Resta, 2011, p. 807. For further literature on Article 5 C.C. see: Venuti, 2002; Carusi, 1998; D'Arrigo, 1999; Caggia, 2005; Romboli, 1988; Giuffrida, 2000; D'Addino Serravalle, 1983.
[387] This is my personal translation. The original text in italian reads as following: "L'articolo 5 risolve il problema della liceità degli atti di disposizione del proprio corpo. Ispirandosi a imprescindibili esigenze di carattere morale e social, il nuovo codice vieta tali atti non solo quando siano contrari alla legge, all'ordine pubblico o ai buon costume, ma anche quando cagionino una diminuzione permanente dell'integrità fisica." *Relazione del Guardasigilli al Progetto definitivo*, p. 20, par. 37 Consulted at http://www.consiglionazionaleforense.it/site/home/pubblicazioni/collana-studi-storici-e-giuridici/articolo6388.html
[388] Alpa and Ansaldo, 2013, p. 360; Perlingieri, 2010, p. 266.
[389] Resta, 2011, p. 808.
[390] Romboli, 1988, p. 228.
[391] Romboli, 1988, p. 228; Alpa and Ansaldo, 2013, p. 360.

particularly applied by prohibiting the acts of disposition of the human body that cause a permanent reduction of the person´s physical integrity since it is considered an essential condition for human beings to fulfil their duties towards society and family. The norm (…) sees therefore with sympathy the acts of disposal of the human body that benefit others without impairment of physical integrity (…)."[392]

The legal justification behind the twofold regulatory aim of Article 5 C.C. was the understanding of the human body as something external to the person, and capable of being object of rights with economic content.[393] The human body was part of a logic that classified it as personal property and at the same time as a means to achieve important policy objectives of the State.[394] However, the original regulatory aim of Article 5 C.C. changed during the years. The changes concern both the specific limit of "permanent reduction of the person's physical integrity", and the general limits of the act being "contrary to law, public order or good morals".

The way in which the problem of the acts of disposition of the human body was approached and solved in Article 5 C.C. shows the accepted understanding of the relation between the individual and her body at the time of the enactment of the Italian Civil Code. The human body was not seen as an inseparable part of the person, but rather as an autonomous object on which the person could exercise property and personal rights.[395] However, with the entering into force of the Italian Constitution, the protection of the person assumed a central role. The human person is since then understood as something unique and inseparable, composed both by body and mind. It has been argued[396] that this shift of paradigm about the understanding of the human person should lead to a new formulation of the debate around the disposition of the human body and its parts. The set out of the debate should be expressed not anymore in terms of "powers of disposal" (*potere di disposizone*) but instead, in terms of "freedom of deciding about the activities that affect or influence the person´s body".[397]

In present times, Article 5 C.C. is seen as one of the most controversial Articles of the first book of the Italian Civil Code.[398] A first scholarly position claims that

[392] This is my personal translation. The original text in italian reads as following: "*Vietando gli atti di disposizione del corpo che producono una diminuzione permanente della integrità fisica, si fa in sostanza, un'applicazione particolare della norma che vieta l'abuso del diritto, in quanto si considera che l'integrità fisica è condizione essenziale perché l'uomo possa adempiere i suoi doveri verso la società e verso la famiglia. La norma quindi (…) vede con simpatia gli atti di disposizione che senza menomazione della integrità personale giovano agli altri* (…). Cit. in Romboli, 1988, p. 229

[393] Alpa and Ansaldo, 2013, p. 360.

[394] Farneti, 2014, p. 74.

[395] Romboli, 1988, p. 229; Dell'Utri, 2012, p. 421.

[396] Romboli, 1988, p. 229.

[397] Santoro-Passarelli, 1997, p. 51.

[398] Romboli, 1988, p. 225.

Article 5 C.C. constitutes an expression of the fundamental constitutional principle of the protection of physical integrity,[399] and that the prescribed limitations to the power of disposition of the human body are important and essential.[400] A second scholarly position argues that Article 5 C.C. is an obsolete rule deprived of any real meaning,[401] a rule that is inadequate for solving the problems posed by new ways of disposing of the human body.[402] A third scholarly position considers that article 5 C.C. is just a piece – and not that important – of a multiplicity of rules and principles (national and international) that should be taken into consideration when analysing the acts of disposition of the human body.[403]

This books deems the first opinion preferable: Article 5 C.C. is still nowadays an essential rule for the regulation of the acts of disposition of the human body. However, Article 5 C.C. should be interpreted in accordance with modern constitutional values and other national and supranational principles and rules. This idea will be further developed in the following sections.

7.3 The notion of physical integrity in Article 5 C.C.

At the time the Italian Civil Code was enacted, the interpretation of the notion of "physical integrity" included in Article 5 C.C. did not cause any particular problems. Indeed, at the time, the concept of physical integrity was uniformly defined as the absence of physical impairments or diseases.[404] During the period previous to the enactment of the Italian Constitution, the specific limit of the "permanent diminution of the physical integrity" under Article 5 C.C. was understood according to a quantitative and anatomic criterion, i.e. the limit applied only if the act of disposition implied an irreversible physical impairment.

After the coming into force of the Italian Constitution, the debate around the relation between the person and her body suffered a radical change of perspective. The debate was no longer formulated in the terms of a limited right of disposition of the human body according to the rigid philosophy that inspired the enactment of Article 5 C.C.[405] Instead, the debate was formulated in the terms of the freedom of the individual to determine what it is best for what concerns her physical being.[406]

[399] Mantovani, 1983, p. 145, cit. in Romboli 1988, p. 225
[400] Guzzon, 1967, p. 397, cit. in Romboli, 1998, p. 225.
[401] Cherubini, 1978, p. 98-99.
[402] Bessone & Ferrando, 1983, p. 157.
[403] Resta, 2011, p. 809.
[404] D'Addino Serravalle, 1983, p. 101.
[405] See Chapter 7 on Article 5 C.C.
[406] Veronesi, 2011, p. 145.

In fact, after a number of Constitutional Court cases[407] involving the right of transsexuals to modify their bodies, the relation between the notions of physical integrity and health began to be object of consideration among Italian scholars. It was maintained that health is a broader concept and includes the one of physical integrity. [408] The latter view has remained unchallenged by the widely acknowledged contemporary understanding of the right to health under Article 32 Cost.[409] According to this contemporary understanding, health should be seen as a dynamic and relative concept. [410] Dynamic, because it is a means to accomplish the complete development of the human personality.[411] Relative, because it varies from one person to another, and depends on the level of development of a certain society.[412] Health is a value in constant transformation that has both a protective and promotional nature. [413] In contrast, physical integrity is considered to be a static notion[414] that refers exclusively to the individual's physical wellbeing.[415]

Italian scholars have also differentiated the notions of physical integrity and health based on a qualitative criterion. While health is a constitutional value that expresses the person's interest to protect, enhance or recover the best possible psychophysical conditions, physical integrity is not a value in itself but a concept that makes reference to the biological processes of the human organism and can bear relevance only in relation with a value (e.g. health).[416]

The modern views on the relation between the concepts of health and physical integrity led also to the re-interpretation of the notion of physical integrity as included in Article 5 C.C.[417] It is now sustained that the latter notion also comprehends the notion of mental health. The understanding of the person as a unitary and indivisible entity brings closer, almost to the point of coincidence, the notion of physical integrity under Article 5 C.C. and the notion of health under Article 32 Cost.[418]

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[407] See Cort. Cost. 24 maggio 1985 n. 161. For a detailed explanation of the Italian legislation and case law on the more general matter of sex change see Palmeri, 2010, p. 729.
[408] Romboli, 1988, p. 235 with further reference.
[409] D'Arrigo, 2001, p. 1009. Ceccherini, 1978, p. 4-5; Cherubini, 1978, p. 80-86; Dogliotti, 1982, p. 87; Perlingieri, 1982, p. 1021; Romboli, 1988, p. 235.
[410] Alpa and Ansaldo, 2013, p. 361.
[411] Dell'Utri, 2012, p. 441.
[412] Busnelli and Breccia, 1978, p. 4-5; Cherubini, 1978, p. 80-86; Dogliotti, 1982, p. 87.
[413] D'Arrigo, 2001, p. 1009
[414] Alpa and Ansaldo, 2013, p. 361.
[415] Ceccherini, 1978, p. 4-5; Cherubini, 1978, p. 80-86; Dogliotti, 1982, p. 87; Perlingieri, 1982, p. 1021.
[416] D'Arrigo, 2001, p. 1009
[417] D'Arrigo, 2001, p. 1009; Perlingieri, 2010, p. 267.
[418] Romboli, 1988, p. 235.

Some[419] have argued that the limit of the "permanent reduction of the person's physical integrity" under Article 5 C.C. has lost relevance for two reasons. Firstly, because of the introduction by special legislation of several derogations, for example the laws on gratuitous organ donation.[420] Secondly, because in interpreting the concept of "physical integrity", the Constitutional Court in substance has made the content of this concept identical with the content of the fundamental right to health.[421]

The now prevalent opinion in Italian case law and legal literature maintains that the diminution of the physical integrity has to be evaluated according to a qualitative criterion, considering the person in its individuality but also in relation with his equals.[422] According to this understanding, the limit of the "permanent reduction of physical integrity" under Article 5 C.C. applies when the act of disposition caused an injury that substantially modifies the way of being of the individual. The alteration of the way of being of the person has to be measured in relation to her environment, when her capacity of "relational life" (*vita di relazione*) is permanently diminished.[423] Moreover, the limit of the permanent reduction of the physical integrity is inapplicable to the acts of disposition of the human body, even in the presence of a diminution of physical integrity, when the purpose of the act is to protect the health of the person, e.g. surgeries and therapeutic experimentation.[424]

7.4 Law, public order or good morals as limits to the validity of private acts under Article 5 C.C.

According to Articles 1345 C.C. and 1346 C.C, illegality means contrariety to mandatory norms, public order or good morals.[425] These three concepts constitute the classic limits to the validity of contracts under Italian law. Similarly, Article 5 C.C. also prescribes that mandatory norms, public order, and good morals are limits to the acts of disposition of the human body.

The concept of public order included in Article 5 C.C. makes reference to those general principles that cannot be modified by the individual. The main source of such general principles is now the Italian Constitution.[426] Therefore, constitutional principles are the normative grounds for the evaluation of the

[419] Alpa and Ansaldo, 2013, p. 362.
[420] For example, see laws n. 458/1967 (kidney transplants); n. 164/1982 (transsexualism); n. 107/1990 (blood taking) n. 483/1999 (liver transplant); n. 219/2005 (blood transfusion activities)
[421] Alpa and Ansaldo, 2013, p. 362; Dell'Utri, 2012, p. 440.
[422] Romboli, 1988, p. 231.
[423] Mantovani, 1983, p.152; Cherubini, 1978, p. 80; Dogliotti, 1982, p. 78. ¡
[424] Romboli, 1988, p. 236.
[425] On the illegality of contracts and the concepts of public order and good morals see Part 3 Chapter 5.2.
[426] Romboli, 1988, p. 231 with further reference.

legality and the worthiness of protection of the acts of disposition of the human body.[427] It is a widespread opinion among Italian scholars that the general clause of public order included in Article 5 C.C. must be interpreted in accordance with the fundamental values of the constitution.[428]

The modern meaning of the notions of public order and good morals under Article 5 C.C. takes both the individual and social dimensions of the acts of disposition of the human body into account. This new meaning is no longer based on the system of controls over the acts of disposition of the human body and its parts stemming from property and contract law rules[429] under the traditional *diritto civile.*[430] Instead, this new meaning is based on the interaction between public law and private instruments.

7.5 Concluding remarks on the validity of contracts on human tissue under Article 5 C.C.

There is an evident parallel between the classic limits to the validity of contracts under Italian law (mandatory norms, public order and good morals) and the limits to the acts of disposition of the human body prescribed by Article 5 C.C. (law, public order and good morals). It seems logical to assume that the modern understandings of the limits to the validity of any contract should apply in the same way to the limits to the acts of disposition of the human body, including the disposition of human tissue.[431] Constitutional principles, values and fundamental rights fill the content of open norms or general clauses such public order and good morals. The additional limit of the "permanent reduction of the physical integrity" included in Article 5 C.C. has also been understood in accordance to constitutional values: the notion of physical integrity should be interpreted now in relation to the constitutional value of the human health. This latter notion bears relevance not only for the interpretation of Article 5 C.C. but also for the one of Article 50 C.P. The following chapter analyses this provision of the Penal Code and its relation with Article 5 C.C.

[427] C. Perlingieri, 2010, p. 267.
[428] D'Arrigo, 2001, p. 1009
[429] Resta, 2011, p. 809.
[430] *Diritto privato* (private law) is a broader notion than *diritto civile* (literally: "civil law"). Private law includes both commercial law (*diritto commerciale*) and *diritto civile*, which is the part of private law different than commercial law.
[431] On these modern understanding see subsection 5.2.3

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Chapter 8

Contracts on human tissue and Article 50 of the Italian Penal Code

CHAPTER 8 Contracts on human tissue and Article 50 of the Italian Penal Code

8.1 Overview

Article 50 C.P. – together with Article 5 C.C – regulated the acts of disposition of the human body and its parts before the entry into force of the Italian constitution and constitutes the legal bases for the doctrine of consent on interferences in one's body. Section 8.2 analyses this doctrine and section 8.3 analyses the relation between Article 50 C.P and Article 5 C.C. Section 8.4 provides some concluding remarks on the effect of the validity of contracts on human tissue.

8.2 Article 50 C.P. and the doctrine of consent on interferences in one's body

As a general rule, the criminal liability for the violation or threatening of a right is excluded in case of consent of the right holder. In Italian criminal law this rule is laid down in Article 50 C.P.: "The one who violates or threatens a right with the consent of the person who can validly dispose of this right, is not punishable."[432]

A typical case in which Article 50 C.P. bears relevance are violations of one's physical integrity committed with the consent of the right holder, for example in the medical sphere.

For the regulation of the validity of contracts on human tissue, Article 50 C.P. is important because it constitutes the legal basis for the doctrine of consent on interferences in one's body elaborated by courts and scholars. Indeed, for issues of consent related to acts of disposition of the human body under Article 5 C.C., private law scholars refer to this criminal law doctrine.[433]

According to Italian scholars, the cause of justification (i.e. the consent of the right holder) included in Article 50 C.P. has exonerating efficacy with regard to injuries to the person, if these injuries do not result in a permanent impairment that affects negatively the social value of the person.[434] Furthermore, the consent of the right holder has to meet two conditions in order to be considered valid. Firstly, the person must have the full capacity to understand the effects of the injury (internal condition). Secondly, the right has to be objectively alienable (external condition).[435]

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[432] This is my personal translation. The original text in italian reads as following: "*non è punibile chi lede o pone in pericolo un diritto, col consenso della persona che può validamente disporne*."
[433] Cendon & Baldassari, 2006, p. 67.
[434] Cendon & Baldassari, 2006, p. 67. For case law see: Cass. Pen. 16 giugno 1998, n. 9326.
[435] Seminara, 2011, p. 209.

The internal condition entails that consent must come from a person that wants and fully understands the content and effects of the act of disposition.[436] The form of the expression of will is irrelevant here. What matters is the intellectual foundation of the decision and its relation to the right holder's self-determination. Only a genuine free will constitutes a valid consent that can exclude the illegality of the infringement of a right.[437]

Concerning the external condition, Article 50 C.P. contains a blanket ground of exoneration: the consent of the right holder exonerates the perpetrator if the right violated or threatened is alienable, but the C.P. does not indicate what should be considered as an alienable right.[438] In fact, according to the report of the Ministry of Justice accompanying the final draft of the Italian Penal Code (*Relazione ministeriale sul progetto del codice penale*), "the criminal legislature cannot assume the task of enumerating the alienable rights. Rules, limits and statements on this matter can be found in every branch of law, private and public, written and customary, and the interpreter must look at such sources when deciding on whether or not the consent validly expressed has the efficacy to exonerate from criminal liability."[439] The drafters of the penal code considered that the open norm of Article 50 C.P. was to be filled with content by reference to the rules on the (in)alienability of rights scattered all over the legal system.[440]

8.3 Relationship between Article 50 C.P. and Article 5 C.C.

This interpretation of Article 50 C.P. was inspired by a horizontal[441] vision of the legal system, followed by Italian jurists at the time of enactment of the C.P. (but no longer followed today). This vision considered legal norms to be absolutely coherent with each other and aligned at the same hierarchical level. Under this understanding, Article 5 C.C. could fill the blanket ground of exoneration of Article 50 C.P. Consent worked as a ground of exoneration if the acts of disposition of the human body did not entail a permanent reduction of the

[436] Seminara, 2011, p. 210.
[437] Romano, 1995, p. 500.
[438] Seminara, 2011, p. 210.
[439] This is my personal translation, the original reads as following: *"(…) il legislatore penale non può arrogarsi il compito di far l'elenco dei diritti disponibili. La materia trova regole, limiti, statuizioni in ogni ramo del diritto, privato e pubblico, scritto e consuetudinario, e l'interprete a tali fonti deve attingere, per decidere se il consenso validamente manifestato abbia efficacia discriminante*". In Lavori preparatori del codice penale e del codice di procedura penale, volume V, parte I, progetto definitivo di un nuovo codice penale con la relazione del guardasigilli on. Alfredo Rocco, ministero della giustizia e degli affari del culto, 1929, p. 93.
[440] Seminara, 2011, p. 211.
[441] This vision is characterized as horizontal because it does not take into consideration a hierarchical based system of law sources. According to a horizontal vision of the legal system all law sources hold the same value. Seminara, 2011, p. 211.

person's physical integrity, or when they were not contrary to law, public order or good morals.[442]

When drafting Article 5 C.C., the Italian legislator of 1942 had the judgment of the Court of Cassation in the famous Naples transplant case in mind.[443] In this judgment,[444] the Court sustained that consent under Article 50 C.P "(…) has the efficacy of excluding the crime only when it is directed to authorize a damage to the body that does not make the individual physically and socially unsuitable to fulfil his duties towards the family and the State."[445]

Arguably, both Article 50 C.P. and Article 5 C.C. reflected the same ideological principles and a specular relation links these two articles: Article 5 C.C. could work as a criterion for the interpretation of Article 50 C.C. and vice versa. In this line of reasoning, Alpa has argued that Article 5 C.C. implies the consent of the right holder.[446] However, according to a critical opinion in Italian legal literature, this intertwined relation led courts and scholars to interpret Article 50 C.P., which is a criminal norm in favour of the accused person, in the light of a norm (Article 5 C.C.) that works against the accused person because it prohibits the acts of disposition of her human body.[447] As a consequence, Article 50 C.P. ended up excluding the exonerative capacity of consent completely, when the act of disposition of the human body implied a permanent reduction of physical integrity.

Even though both provisions have the same ideological background, there was an evident mismatch between the regulatory aims of Article 50 C.P. and Article 5 C.C.: while the Civil Code provision answered to the legislative intent to allocate to the individual the right to contract on and commercialize her body,[448] the Penal Code rule aimed at recognizing consent as a cause of exoneration.

According to a modern understanding of the legal system, norms do not always answer to the same ideological precepts, and do not always hold the same rank in the hierarchy.[449] Therefore, the blanket ground of exoneration of Article 50 C.P. cannot be simply filled with the content of the various legislative prohibitions found in other parts of the legal system. Under this understanding, Article 5 C.C. as such does not constitute an insurmountable limit to the scope of

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[442] Seminara, 2011, p. 211.
[443] See section 7.2.
[444] Cass. Pen., 31 gennaio 1934. *Corte di Cassazione del Regno*.
[445] "(…) *il consenso ha efficacia di escludere il reato solo quando sia rivolto ad autorizzare un danno al corpo che non renda l'individuo fisicamente e socialmente inidoneo all'adempimento dei suoi doveri in rapporto alla famiglia e allo Stato*." Cass. Pen., 31 gennaio 1934. *Corte di Cassazione del Regno*.
[446] Alpa, 2005, p. 267.
[447] Seminara, 2011, p. 214.
[448].Cass. Pen. Sez. Un. 18 dicembre 2008, n. 337.
[449] Seminara, 2011, p. 211.

application of Article 50 C.P. anymore. However, Article 5 C.C. still constitutes a first filter for the interpretation of Article 50 C.P. insofar as Art 5 C.C. is interpreted in consonance to modern constitutional principles. The specific limit of Article 5 C.C. of the "permanent reduction of the person's physical integrity" should be now understood in the light of the constitutional notion of health.[450] Moreover, the constitutional principles of self-determination and solidarity should also play a role in determining the consequences of consent under Article 50 C.P.[451] The principle of self-determination[452] should be understood as the foundation of a liberal State where the sphere of action of the individual is strongly connected to the *neminem laedere* rule. The principle of solidarity, in this regard, refers to the duty of state institutions to promote the full development of the human person.

8.4 Concluding remarks

Article 50 C.C. bears relevance for the determination of the limits to the validity of contracts on human tissue because it serves as the basis for the doctrine of consent in interferences in one's body. Article 50 C.P. and the doctrine of consent could contribute to determine the validity of contracts, for example in cases where a person has authorized, by signing a contract, a medical intervention that causes permanent damages to her health, e.g. the *inter vivos* transfer of a cornea. Both the internal and external conditions for consent to be valid apply in the determination of the validity of a contract on human tissue. The internal condition (the capacity of the person to understand the effect of the injury) finds a parallel application in the contract law doctrine of annullability of the contract because of incapacity.[453] The external condition (the right has to be objectively alienable) has been interpreted in accordance with the constitutional notion of health – like the notion of "permanent reduction of physical integrity" under Article 5 C.C. – and the constitutional principles of solidarity and self-determination.

[450] On the relation between the notion of physical integrity in Article 5 C.C. and the constitutional notion of health see Subchapter 7.3 above.
[451] Seminara, 2011, p. 211.
[452] This principles is strongly connected to the personalistic principle described in section 6.4.
[453] See subsection 5.3.1.

9

Chapter 9

The debate on the prohibition of financial gain from the human body and its parts

CHAPTER 9 The debate on the prohibition of financial gain from the human body and its parts

9.1 Overview

The general principle according to which the human body and its parts, including human tissue, cannot be a source of financial gain can be described with the expression 'prohibition of financial gain'. Firstly, this chapter identifies the supranational and national legal sources from which the general principle of financial gain has been distilled (section 9.2). Secondly, this chapter analyses two different Italian scholarly positions on the prohibition of financial gain (sections 9.3 and 9.4). Finally, this chapter identifies the scope of application of this prohibition and provides some concluding remarks (section 9.5).

9.2 The principle of prohibition of financial gain from the human body and its parts: legal bases

According to Giorgio Resta, Article 5 C.C. as such does not subordinate the lawfulness of the acts of disposition of the human body to the gratuitousness of the acts, i.e. the absence of remuneration. The gratuitousness requirement could not be deduced by reference to the notion of public order or good morals either.[454] In his opinion, the prevailing literature[455] affirmed for some time the validity of contracts aimed at obtaining economic profit from a body part or a bodily function. It was only with the coming into force of the sectorial Italian legislation on organ donation and transplants that gratuitousness began to be considered as a general requirement for the lawfulness of the acts of disposition on the human body.[456] The relevant national laws relating to the gratuitousness requirement for organ donation and transplant are:

-The law n. 458/1967, on kidney transplantation (*inter vivos*), particularly Article 1, which allows for the gratuitous disposition of kidney in derogation from Article 5 C.C.,[457] and Article 6, which considers void any compensation in money or other kind of benefit for inducing the donor to dispose of his kidney as null and void (*nulla*). [458]

[454] Resta, 2011, p. 810 with further references.
[455] See for example: Carusi, 1995; Dogliotti 1990; D'Arrigo 1999. For more literature references, see Resta, 2001, p. 810.
[456] Resta, 2011, p. 810 with further references. See Chapter 7 on Article 5 C.C.
[457] Article 1: "*In deroga al divieto di cui all'art. 5 del Codice civile, è ammesso disporre a titolo gratuito del rene al fine del trapianto tra persone viventi*."
[458] Article 6: "*Qualsiasi pattuizione privata che preveda un compenso in denaro o altra utilità in favore del donatore, per indurlo all'atto di disposizione e destinazione, è nulla e di nessun effetto.*"

-The law n. 301/1993 on the taking and grafting of cornea (from cadavers), particularly Article 1, which prescribes the gratuitous donation of cornea,[459]

-The law n. 483/1999 on partial liver transplantation, particularly Article 1, which allows for the gratuitous disposition of a part of the liver in derogation from Article 5 C.C.) ,[460]

-The law n. 52/2001 on the Recognition of the Italian National Register on bone marrow, particularly Article 4, which prescribes that the donation of bone marrow is a gratuitous and voluntary act.[461]

-The legislative decree n. 191/2007,[462] particularly Article 12 that prescribes that the donation of tissues and cells is voluntary and gratuitous. [463]

Article 1 of the law n. 458/1967 and Article 1 of the law n. 483/1999 specifically derogate from Article 5 C.C. (in particular, to the limit of the ´permanent reduction of physical integrity') in what relates to kidney and partial liver transplantation.[464] Furthermore, Article 3 par. 3 of the Law 219/2005 also prescribes the voluntary and gratuitous donation of placenta and blood from the umbilical cord.

Further norms that set limits to the commercialization of human body parts can also be found in the following international and EU legislative provisions:

- Article 4 of the Declaration on the Human Genome and Human Rights 1997,[465]
- Article 21 of the Oviedo Convention,[466]
- Article 8(a) of the UNESCO Universal Declaration on Human Genetic Data 2003,[467]

[459] Article 1: "*La donazione delle cornee è gratuita* (…)".
[460] Article 1: "*In deroga al divieto di cui all'art. 5 del Codice civile, è ammesso disporre a titolo gratuito di parti di fegato al fine esclusivo del trapianto tra persone viventi*".
[461] Article 4: "*La donazione di midollo osseo è un atto volontario e gratuito* (…)".
[462] This legislative degree implements the Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48 (thereafter Tissue and Cells Directive 2004). According to Article 2 of this Directive (and the legislative decree 191/2007), the Directive "shall apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications."
[463] Article 12: "*La donazione di tessuti e cellule é volontaria e gratuita*".
[464] Comandé, 2014, p. 273.
[465] "The human genome in its natural state shall not give rise to financial gains." Declaration on the Human Genome 1997. See fn. 158.
[466] "Prohibition of financial gain. The human body and its parts shall not, as such, give rise to financial gain". See fn. 25.
[467] "(a) Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic

- Article 3 subparagraph 2, lit. c of the Charter of Fundamental Rights of the European Union (CFREU),[468]
- Recital 23 of the European Blood and Blood Components Directive 2002EC,[469]

From the above-mentioned national and supranational provisions, Italian legal literature has distilled the general principle that forbids to use the human body and its parts as a source of financial gain. Some authors[470] use the term 'gratuitousness principle' (*principio di gratuità*) to refer to the same principle that other authors[471] call 'extrapatrimoniality principle'. This book will use the expression 'prohibition of financial gain'.[472]

Two main positions can be identified in Italian scholarly works on the prohibition of financial gain. Some claim that the acts of disposition of most human body parts should always be gratuitous and that the human body and its products, as a general rule, cannot be object of a patrimonial right.[473] Others maintain that under certain circumstances the acts of disposition of the human body and its parts can be performed in exchange of remuneration and that the separated parts of the human body have a patrimonial character.[474]

One may therefore observe a paradigm shift in the understanding of Article 5 C.C. by Italian scholars: while the traditional view considered the human body as a possible source of economic profit, according to the contemporary views the human body and its parts, in principle, cannot be a source of financial gain. The following sections (9.3 and 9.4) will outline these contemporary opinions.

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data or biological samples (…)". UNESCO, Universal Declaration on Human Genetic Data, 2003 (Hereafter Declaration on Human Genetic Data 2003).

[468] "2. In the fields of medicine and biology, the following must be respected in particular: (…) c. the prohibition on making the human body and its parts as such a source of financial gain." Charter of Fundamental Rights of the European Union (2012/C 326/02) Published in the Official Journal of the European Union C 326/391 the 26th of October 2012. See fn. 26

[469] "(…) (A)ll necessary measures should be taken to encourage voluntary and unpaid donations through appropriate measures and initiatives and through ensuring that donors gain greater public recognition, thereby also increasing self-sufficiency. The definition of voluntary and unpaid donation of the Council of Europe should be taken into account". Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC OJ L33/30 (hereafter European Blood and Blood components Directive 2002).

[470] See for example Messinetti, 2001 and Venuti 2001.

[471] This is a literal translation from the Italian expression "*extra-patrimonialità*", used in Italian literature. See e.g. Resta, 2011, p. 816.

[472] This book adopts the terminology used by Article 21 of the Oviedo Convention.

[473] Resta, 2011.

[474] Alpa e Ansaldo, 2013; Romboli, 1988.

9.3 First position: Resta and Dell' Utri

According to Resta, it is hard to find a single regime of disposition and transfer of rights that applies to all parts of the human body. Firstly, because the law establishes different rules for different objects: the body, body parts, organs, (single and double), tissue, gametes, etc. Secondly, because the law provides different rules for different uses: therapeutic purposes, scientific research, commercial uses, and altruistic uses.[475] However, he identifies a trend in European law towards a highly protective regime, characterized by the marginalization of market transactions on the human body and its parts.[476] According to him, this highly protective regime applies to most human body parts and finds its reflection in Article 3 CFREU, which states that the body and its parts should not as such be made a source of financial gain. Resta calls the principle embodied in Article 3 CFREU, 'extrapatrimoniality' (*extra-patrimonialità*).[477]

The extrapatrimoniality principle was already embodied in Article 21 of the Oviedo Convention and at the national level, in Article 16-5 of the French Civil Code (thereafter: Cod. Civ.): "(t)he agreement having the effect of conferring a patrimonial value to the human body, its elements or its products are void".[478]

According to Resta, the principle of extrapatrimoniality is one of the axes of the modern legal status of the person (*statuto giuridico della persona*).[479] He maintains that the meaning of the extrapatrimoniality principle is twofold: its first meaning revolves around the general rule of gratuitousness of the acts of disposition of the human body, and its second meaning precludes that the human body and its products become the object of a patrimonial right (*diritto patrimoniale*).[480]

The first meaning of the extrapatrimoniality principle leans on the general rule of gratuitousness of the acts of disposition of the human body. This rule prohibits economic profit in exchange for body parts or bodily functions and considers the transactions entered under such conditions as void.[481] The gratuitousness rule can be found in the aforementioned supranational legislative provisions on the prohibition of financial gain.

[475] Resta, 2011(1), p. 54, with further references.
[476] Resta, 2011 (1), p. 55, with further references.
[477] See fn. 471 above.
[478] This is my personal translation, the original text in French reads as follows: "*Les conventions ayant pour effet de conférer une valeur patrimoniale au corps humain, à ses éléments ou à ses produits sont nulles*".
[479] Resta, 2011, p. 817. Ferrando, 2002, p. 761; Messinetti, 2001, p. 1; Galasso, 2001, p. 911; Venuti, 2001, p. 827; Morozzo della Rocca, 2004, p. 98.
[480] Resta, 2001, p. 817.
[481] Resta, 2001, p. 821.

According to Resta, the gratuitousness rule plays two complementary functions. On the one hand, it excludes the acts of disposition of the human body from the market logic, and encourages solidarity and gift based agreements.[482] On the other hand, it protects the natural persons involved in the acts of disposition of the human body and/or its parts. The absence of monetary incentives reinsures that the person's consent and will are given freely, as an act of self-determination.[483]

The second meaning of the extrapatrimoniality principle consists in that the human body and its parts cannot be the object of a patrimonial right.[484] The understanding of the rights on the human body as extrapatrimonial deprives these rights of any economic content. If this connotation of the rights on the human body is taken to its logical conclusion, it would have effects on the compensatory and restitutionary protection in the cases of non-authorized economic use of human tissue.[485] The absence of an economic content, and therefore, also the absence of a protection of the patrimonial aspects of the rights on the human body, would limit these rights to a simple *droit de defense*.[486] In other words, it would be excluded to act for the restitution of the profits illegally obtained. Only a compensatory action (*azione resarcitoria*) would be admitted.[487] According to Resta, "personality rights are often referred to as "*droits de defense*" or "*Abwehrrechte*", which means that they are not aimed at allocating wealth, but at enforcing norms of civility and respect in interpersonal relationships".[488]

This second meaning of the extrapatrimoniality principle implied the abandonment of the Italian traditional position according to which separated parts of the human body could be object of property rights.[489] The personalistic approach, according to which the person's prerogatives on her body and its parts are derived from personality rights, is coherent with this understanding of the principle of extrapatrimoniality.[490]

Dell'Utri defends a similar position. According to him, it is no longer possible to think of separated body parts in terms of property rights.[491] Similarly to Resta,

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[482] Rodotà, 2006, p. 126.
[483] Resta, 2011, 820; Galasso, 2001, p. 935.
[484] Resta, 2011, 817.
[485] Resta, 2008.
[486] Resta, 2011, p. 818; Resta, 2011(1), p. 36. For a similar position in French literature see: Bellivier-Noiville, 2006, p. 115. The famous case Moore v. the Regents of the University of California, 793, P.2d 479 (Cal. 1990) follows a similar approach.
[487] Resta, 2011, p. 818
[488] Resta, 2011 (1), p. 37.
[489] This traditional position was defended among others by Lenti, 1993; Criscuoli, 1985.
[490] Zatti, 2000, p. 64.
[491] Dell'Utri, 2014, 501. In 2005, a Napoli Tribunal examined the only case, to my knowledge, that has reached the Italian courts in direct relation to property rights on human tissue. In this case, the Tribunal explicitly reject the property rights approach while arguing for a personality rights

he derives from the provisions of Article 3 of the CFREU and 21 of the Oviedo convention the requirement of gratuity for the transfer of separated human body parts, as such. [492]

Regarding the interpretation of the expression "as such", included in the aforementioned articles, Dell'Utri suggests that it should be understood as to limit the prohibition of financial gain to the use of human material for the purposes of relevant existential or biological experiences (e.g. blood transfussions, transplants, clinical or pharmacological experimentation).[493]

9.4 Second position: Romboli, Alpa, Ansaldo

In 1988, Romboli[494] reported that private law literature unanimously sustained that a part of the human body becomes a good or thing (*cosa*) from the moment of its separation from the human body,[495] and the person from whom the body part was detached acquires over it a property right with patrimonial content.

Nowadays, private law literature does no longer unanimously sustain this, given the above mentioned national and supranational prohibitions on using body parts as a source of financial gain. Italian literature is now divided: some authors (see 9.3 above) question the possibility of existence of patrimonial rights on human body parts altogether, while other authors, such as Alpa and Ansaldo, consider the above mentioned prohibitions as exceptions to the general rule of free disposition of human body parts under Article 5 C.C.

According to Alpa and Ansaldo,[496] one can speak of a property right (*diritto di natura reale*) of fruition and unlimited disposition of the detached parts of the human body. According to these scholars, the limit to the acts of the disposition can be found in the general prohibition of the 'permanent reduction of the person's physical integrity' under Article 5 C.C. For example, a person could not

model based on articles 2 and 32 of the Italian constitution. Trib. Napoli sez. I 14 gennaio 2005, n. 377. In Diritto e giurisprudenza, 2008, fasc. 2, pp. 300-310. Cited in Resta, p. 819, ft 56.

[492] Dell'Utri, 2014, 502.

[493] Ibid.

[494] Romboli, 1988, p. 362: " (…) *la dottrina privatistica è infatti unanime nel ritenere che, al momento della separazione, la parte del corpo diventa una cosa e il soggetto acquista sulla stessa, a titolo originario, un diritto di proprietà avente contenuto patrimoniale*".

[495] The more ancient Italian literature (De Cupis, 1982, p. 181) argued that nothing prevents a person to dispose of the part of her body even before the detachment from her body has occurred. The only limit was the prohibition of attributing to another person an irrevocable power of injury by making the detachment of the part from its body mandatory: such an act of disposition was considered void. See De Cupis, 1982, p. 181: "(…) *nulla vieta che il soggetto possa disporre della parte staccata anche prima che il distacco sia effettivamente avvenuto. Al contrario, dovrebbe ritenersi invalido perché illecito un negozio inteso ad attribuire ad altro soggetto un potere irrevocabile di lesione rendendo cosí obbligatorio il distacco e con esso la trasformazione della parte del corpo in res."* For more recent literature in the same line see Alpa, 2005, p. 270.

[496] Alpa e Ansaldo, 2013, p. 394.

then sell an arm, a leg, an eye or any other vital part of her body.[497] However, if an act of disposition of the human body does not entail a permanent reduction of the person's physical integrity, then, as a general rule, the relation between the person and the detached part of her body can be described in terms of a possibility of fruition and exchange.[498]

In order to take position on the general prohibition of financial gain, this book considers necessary to firstly determine its scope of application. The following section will address this issue.

9.5 Scope of application of the prohibition of financial gain

The determination of the scope of application of the prohibition of financial gain under Italian law is difficult. The coordination between the prohibitory rules present in the Italian sectorial legislation,[499] and the general principle of prohibition of financial gain laid down in the supranational provisions mentioned under 9.1 above is intricate. On the one hand, because of the plurality of sets of rules concerning the human body and its parts.[500] On the other hand, because of the undeniable generality of the prohibition of making the human body and its parts a source of financial gain.[501]

According to Resta, two initial remarks are necessary to begin unravelling the application of the prohibition of financial gain on Italian law. The first remark regard the scope of application of this principle as enounced in Article 3, paragraph 2, lit. c of the CFREU. This provision limits the scope of application of the prohibition of financial gain to the fields of medicine and biology.[502] This limitation excludes a number of acts of disposition of the human body for profit in other sectors, e.g. prostitution, work contracts in the field of sports, and the commercial use of human body images.[503]

The second remark is that Article 21 of the Oviedo Convention and Article 3, paragraph 2, lit. c CFREU prescribe that the human body and its parts shall not,

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[497] Alpa e Ansaldo, 2013, p. 394: "*Per le parti staccate del corpo si può parlare di un vero e proprio diritto di natura reale e quindi di godimento e di disposizione senza limiti. Il problema è se mai quello, già esaminato, del divieto di atti che producano una limitazione permanente dell'integrità fisica. Dunque il soggetto non potrebbe alienare un braccio, una gamba, un occhio o altra parte vitale del suo corpo (…)*".

[498] Alpa e Ansaldo, 2013, p. 394; Alpa, 2005, p. 270. See also Dogliotti, 1982, p. 82.

[499] Laws n. 458/1967 (partial transplant of liver); n. 483/1999 (transplants of liver); n. 91/1999 (transplants of organs in general); n. 52/2001 (one marrow transplant); n. 301/1993 (cornea transplant). See section 9.2. above.

[500] Zatti, 2008, p. 84; Rodotà, 1994, p. 191.

[501] Resta, 2011, 821.

[502] Zatti, 2008.

[503] Resta, 2011, p. 822.

as such, give rise to financial gain.[504] The expression '*as such'* refers to the human body and its parts when they have not been object of transformation.[505] If the recipient of human tissue transforms them in any way, for example by fixing them in paraffin blocks, then the material would fall outside the scope of the abovementioned articles.

Following Resta's approach, the prohibition of the commercialization of the human body and its parts is only directed to the contracts concluded between the first transferor (donor) and the first recipient. The subsequent contracts on the human body or its parts, concluded between the first recipient and further recipients, fall outside the scope of the prohibition of financial gain.[506]

Thus, three types of contractual relations should be distinguished: (1) gratuitous contracts concluded between the first transferor (donor) and the first recipient (2) non-gratuiotous contracts concluded between the donor and the first recipient, (3) contracts concluded between the first recipient and further recipients (e.g. the material transfer agreements).

Arguably, the limits to the validity of contracts on human tissue discussed in the previous chapters apply to these three types of contractual relationships. However, because of the scope of application of the prohibition of financial gain, the last two types of contracts described above present special ethical and legal issues that deserve independent attention. In the case of non-gratuitous contracts between the first transferor and the first recipient, the prohibition of financial gain would apply. In the case of contracts concluded between the first recipient and further recipients the prohibition of financial gain does not apply. For this reason, Chapter 10 will be devoted to the problems discussed in Italian literature regarding the validity of non-gratuitous contracts on human tissue concluded between the first transferor and the first recipient. Chapter 11 will focus on the analysis of material transfer agreements (MTAs), as examples of contractual practices between the first and further recipients of human tissue.

[504] See Article 3 CFREU and Article 21 of the Oviedo Convention. In a similar way, Article 4 of the Declaration on the Human Genome 1997 refers to "the human genome in its natural state".
[505] Resta, 2011, p. 812.
[506] Resta, 2001, p. 822.

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Chapter 10

Validity of non-gratuitous contracts on human tissue concluded between the first transferor and the first recipient

CHAPTER 10 Validity of non-gratuitous contracts on human tissue concluded between the first transferor and the first recipient

10.1 Preliminary remarks

The non-gratuitous acts of disposition of human tissue explicitly allowed by Italian legislation are limited to few categories concerning the industrial and commercial spheres. These include the transfer for profit of bodily waste products or reproducible elements (teeth, hair, nails).[507] The explanatory report to the Oviedo Convention already excepted such transfers from the general prohibition in Article 21 of the Convention for the reason that these transfers do not constitute an "affront to human dignity".[508]

While the lawfulness of the transfer for profit of bodily waste products and reproducible elements is quite clear, some difficulties arise when the object of the transfer for profit is human tissue for the purposes of scientific research and possible commercial uses thereof. These types of contracts are neither explicitly prohibited nor explicitly allowed by law.

This chapter explores the arguments brought forward by Italian scholars against or in favour of the lawfulness of such transfers.

10.2 Non-gratuitous contracts for the purposes of research and possible commercial uses

10.2.1 Overview

The non-gratuitous transfer of human tissue (including DNA samples) from the first transferor to the first recipient for purposes of scientific research and possible commercial uses thereof is an issue of debate among legal scholars, economists and bioethicists. Several arguments have been raised in favour and against the lawfulness of these transactions. These arguments can be divided into seven groups, corresponding to seven different viewpoints: 1) the relation between the general prohibition of financial gain and the legal regime of the acts of disposition of the human body (Subsection 10.2.2), 2) the adequate protection of human dignity (Subsection 10.2.3), 3) the adequate protection of personal data and privacy (Subsection 10.2.4), 4) the adequate protection of the physical integrity and health (Subsection 10.2.5), 5) the positive and negative consequences of delegating the collection of human tissue to the market (Subsection 10.2.6).

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[507] Alpa and Ansaldo, 2013, p. 394.

[508] Explanatory Report to the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine ETS n. 164, paragraph 133.

10.2.2 The relation between the general prohibition of financial gain and the legal regime of the acts of disposition of the human body

Resta has argued that the legal regime governing the acts of disposition of the human body does not longer rest on the old paradigm underlying the enactment of Article 5 C.C. [509] In Resta's opinion, according to the contemporary understanding of the rights on one's body, which relies on the principles of autonomy and human dignity, the person´s sphere of action in relation to the choices about her body has expanded insofar as these choices do no longer need to satisfy higher interests of the State. However, this expansion does not entail the possibility of trading human tissue on the market. The increase of the range of action of the individual finds its basis in a regulatory framework composed by a plurality of legal sources whereby public and private law permanently interact.[510] The new legal regime of the acts of disposition of the human body emerges from the interplay of different national and supranational legal sources that orbit around the paradigms of self-determination, solidarity, gratuity and external controls. These paradigms are part of the modern understanding of the notion of public order.[511] In this line of reasoning, according to Resta, if the notion of gratuity is considered part of the public order clause under Article 1418, subparagraph 2, C.C.,[512] then a transfer for profit of human tissue is illegal[513] because its cause is contrary to public order.[514]

10.2.3 The adequate protection of human dignity

When pleading against the lawfulness of transfers for profit of human tissue, some Italian scholars refer to the link between the prohibition of financial gain laid down in Article 3 CFREU and Article 21 of the Oviedo Convention on the one hand and human dignity on the other. These scholars maintain that there exists an underlying risk of commodification of the human body resulting from such transfers, which is problematic from the viewpoint of human dignity.[515] For a critical discussion of this argument with reference to this book's own position see Part 6 section 22.3.

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[509] According to this old paradigm, the body was an object with patrimonial character, clearly differentiated from the person herself, and a means to satisfy the higher interest of the State.

[510] Resta, 2006, p. 621.

[511] Resta, 2006, p. 621.

[512] Article 1418, par. 2 C.C. "*Producono nullità del contratto la mancanza di uno dei requisiti indicati dall'articolo 1325 , l'illiceità della causa, l'illiceità dei motivi nel caso indicato dall'articolo 1345 e la mancanza nell'oggetto dei requisiti stabiliti dall'articolo 1346* ". On Article 1418 see section 5.2.

[513] Venuti, 2002, p. 187.

[514] Resta, 2011, p. 826, with references to French scholarly works on the relation between the human body and public order (Hennette-Vauchez, 2004; Vincet-Legoux, 2001).

[515] Resta, 2011, p. 826 with further references. Resta, 2011 (1), p. 56 with further references.

10.2.4 The adequate protection of personal data and privacy

The transfer of human tissue always involves the transfer of genetic data (since these samples contain the person's genotypic information).[516] Biobanks usually connect human tissue to genealogical and clinical data of the person from whom the material was extracted. As a consequence, and unless the tissue samples are anonymized, the samples that are stored in biobanks are susceptible of constituting a source of personal information. It has been maintained that the transfer of the data included in human tissue should be thus guided by the set of norms and principles on personal data and privacy.[517]

In Italy, like in the rest of the EU, the set of rules on privacy is particularly restrictive, and one of its main characteristics is the paradigm of non-commercialization. As a consequence, it has been stated that the transfers for profit of human tissue between the donor and the first recipient should be always unlawful. [518]

10.2.5 The risks to the person's physical integrity and health

In favour of the lawfulness of the transfers for profit of human tissue, it has been maintained that such transfers do not create any risk for the physical integrity and health of the donor of human tissue. In fact, the most invasive procedure in carrying on research on human tissue is limited to the withdrawal of blood or a biopsy. This kind of research arguably does not diminish the donor's physical integrity or entail a risk for her health. [519]

10.2.6 The positive and negative consequences of delegating the collection of human tissue to the market

From the viewpoint of the negative and positive consequences of delegating the collection of human tissue to the market, the following arguments against the lawfulness of such for profit transfers have been raised:

a) It is inconvenient to delegate to the market the collection of materials that are useful for the whole society. This argument is based on the idea that the State should be the main provider of health services in a system based on the logic of altruism and not on the logic of self-interest.[520]

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[516] Resta, 2011, p. 827; Macilotti, 2009, p. 157.
[517] D'Antonio, 2004. See Part 1 subsection 3.5.1 on the Italian data protection system.
[518] Resta, 2011, p. 828; D'Antonio, 2004, p. 337; Parisi, 2004, p. 385.
[519] Novelli and Pietrangeli, 2011, p. 1033;
Fondazione Smith Klein e Società Italiana di Genetica Umana, 2006, p. 39, <avalable at file:///Users/enriquesantamaria/Downloads/lineeguidaricgenverseletrravanzata.pdf> last accessed 2 November 2019.
[520] Resta, 2011(1), p. 56.

b) From the admission of economic benefits, a discriminatory effect among social classes possibly derives because the sellers in such markets would be the most disadvantaged and poor individuals.[521]

[521] Resta, 2011 (1), p. 56.

Chapter 11

Examples from the contract practice

CHAPTER 11 Examples from the contract practice

11.1 Preliminary remarks

The aim of this chapter is to provide a few practical examples of enforceable contracts for the use of human tissue under Italian law. Additionally, when appropriate, this chapter analyses whether or not, and to what extent, the (relevant) clauses of the various MTAs abide with the legal sources identified in this book applicable to contracts on human tissue.

This chapter analyses two specific MTA contract templates for the transfer of human tissue. The first one is the agreement for the transfer of composed materials and structures for the purposes of research of the "Università degli Studi di Firenze" (hereafter: UniFi MTA).[522] The second one is the contract for the transfer of materials for non-commercial purposes of the "Università degli studi di Torino" (hereafter: UniTo MTA).[523]
The original aim of this chapter was to include in its analysis not only contracts for the transfer and use of human tissue with non-commercial purposes, but also contracts with commercial purposes. However, despite my best efforts, it was impossible to find them. As it will become apparent in the comparative part of this book (Part 5), it was easier to find MTA's templates with commercial purposes enforceable under English law.
For this reason, this chapter (section 11.2) is limited to the analysis of the most common contractual clauses included in MTA's without commercial purposes enforceable under Italian law.

11.2 MTA's without commercial purposes

In this section I will firstly analyse the clauses that are common to both the UniFi MTA and UniTo MTA, to then examine the clauses that are particular to each of them.

The common clauses to both MTA's are the following:

1) Prohibitions of using the transferred materials on humans.[524]
2) Provisions prescribing that the recipient institution of the materials is obliged to obtain the consent of the provider institution (i.e. the University) for the transfer of the tissue to a third party.[525] The inclusion of such clause may answer to the idea that before a transfer to a third party is made, the transferor must guarantee that the consent of the original donor allows for the use of the human tissue that the third party intends to make.

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[522] Accordo per il Transferimento di Materiale composti e strutture a copo di ricerca. Available at: https://www.unifi.it/upload/.../accordo_trasferimento_materiale.rtf. Last accessed: 11 November 2018
[523] Contratto di trasferimento di materiale per scopi non commerciali. Availabale at: www.mut.unito.it/media/0/Material-Transfert-Agreement.pdf. Last accessed 11 November 2018.
[524] Clause 2.2 UniTo MTA; Clause 3 UniFi MTA.
[525] Clause 2.5 UniTo MTA; Clause 7 UniFi MTA.

3) Provisions regarding the publication of the results of the research carried on the transferred human tissue. In particular, both contract templates prescribe that the source of the materials should be cited in any publication by the recipient institution.[526]

The UniTo MTA includes definitions of what commercial purposes and non-commercial purposes mean.[527] Commercial purposes include: the sale, lease, license or transfer of material to a subject that carries an economic activity with the purposes of financial gain. Non-commercial purposes are activities of research, teaching, or other activity without connection with the activities described under the definition of commercial purposes. The UniTo MTA is an agreement for non-commercial purposes.

Similarly, the UniFi MTA excludes the use of the transferred material for the purposes of financial gain, tests, production or sale.[528] In line with this provision, the UniFi MTA prescribes that the transfer of the material must be gratuitous.[529] Since this MTA does not have commercial purposes, the prohibition of financial gain included in it is in line with the scholarly position that argues that the human body and its parts cannot give rise to financial gain.[530] However, the contract does recognize to the transferor institution a property right on the materials.[531] In this sense, the transferred of tissue agreed under the UniFi MTA may be a gratuitous lease of tissue.

On the contrary, the UniTo MTA incudes a provision that allows for the compensation for the transfer of the material.[532] Additionally, this MTA indicates that after the transfer of the materials, the recipient bares the risk for the destruction or loss of the materials.[533] From the wording of this clause it can be derived that the property of the materials passes from the transferor to the receiver of the materials. Arguably, in this case the transfer does not occur under a lease but under another contract (e.g. donation or sale).

Noticeably, both MTA's recognize property rights on the materials object of the transfer, but none of them allows the obtention of profit from it.

Moreover, UniTo includes a contractual provision that indicates that the use of the transferred tissue must abide not only with the Italian laws, but also with the regulations, ethical guidelines and recommendations of international and national organizations regarding human tissue.[534] It is of interest that the contract gives legal binding effect to regulations and other governance instruments that otherwise would not be necessarily legally binding.

[526] Clause 3 UniTo MTA; Clause 9 UniFi MTA.
[527] Clauses 1.8 and 1.9 UniTo MTA.
[528] Clause 4 UniFi MTA.
[529] Clause 12 UniFi MTA.
[530] On the prohibition of financial gain see Chapter 9.
[531] Clause 2 UniFi MTA.
[532] Clause 7.1 UniTo MTA.
[533] Clause 7.4 UniTo MTA.
[534] Clause 2.2 UniTo MTA.

Finally, this MTA includes contractual clauses with definitions and regulation of the possible intellectual property rights.[535]

The UniFi MTA does not include any of the aforementioned contractual clauses but does include one prescribing that the transferor does not provide any warranties or makes any representations on the quality of the materials, or on that the materials do not infringe property rights.[536] This clause is particularly problematic from the point of view of the consent of the original source of the tissue. Arguably, the validity of these MTA's may be challenged in the cases when appropriate consent has not been obtained from the original source. On the one hand, if original source of the material has not consented to the transfer of it, one could argue that the validity of the contract can be challenged on the grounds of the absence of consent. If successful, the consequence of it would be the nullity of the contract. On the other hand, it is also possible to challenge such contract in the cases of mistake or fraud. The consequence, in this latter case would be the annullability of the contract.

Finally, it is striking that none of the analysed MTA's includes a reference to the original source of the materials, or to her consent. Clauses relating to the protection of personal data (health and genetic data) are also surprisingly absent. In fact, Italian data protection laws require the written consent of the original source of the materials for any processing of health and genetic data. It would be desirable to include contractual clauses that indicate that appropriate consent has been obtained for the transfer and processing of the materials and data associated to them.

[535] Clauses 1 and 4 UniTo MTA.
[536] Clause 10 UniFi MTA.

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Chapter 12

Concluding remarks on the limits to the validity of contracts on human tissue under Italian law

CHAPTER 12 Concluding remarks on the limits to the validity of contracts on human tissue under Italian law

12.1 Validity of contracts on human tissue under national law

The limits to the validity of contracts on human tissue under the Italian legal system are not determined in a specific set of norms or statute. Instead, a harmonious reading of the supranational and international norms, the general private norms on the validity of contracts, the specific norms of the civil code (Article 5 C.C.) and penal code (Article 50 C.P.) and the constitutional principles, values and fundamental rights, allow for the creation of a general legal framework within which the limits to the validity of contracts on human tissue can be determined.

Within the Italian doctrine of the invalidity of the contract, the grounds of annullability and nullity bear particular relevance for the determination of such limits. In the case of annullability, both the legal categories of incapacity (e.g. contracts concluded by minors) and vices of the will maybe be useful in the analysis of the validity of contracts on human tissue. The latter legal category (vices of the will), in particular, is relevant for the determination of a valid consent for the conclusion of the contract in the cases of mistake and fraud. Moreover, when the consent for a contract on human tissue involves also an intervention on the person's physical integrity, the internal and external conditions of Article 50 C.P. should also be taken into account. As we have seen, the internal condition – the capacity of the person to understand the effect of the injury – finds already a parallel application in the private law doctrine of annullability. The external condition – the right has to be objectively alienable – has to be interpreted in the light of the constitutional notion of health and the constitutional principles of solidarity and self-determination.

The nullity of the contract is the most severe form of invalidity and may occur either because of the absence of one of its constitutive elements (agreement, object, cause and form) or because the contract is contrary to mandatory norms, public order or good morals. In the former case, it is hard to imagine a contract on human tissue whereby the agreement, the cause or the object are missing. However, according to Italian data protection law, the consent for the processing of genetic health and genetic data (both contained in human tissue) must be given in writing. One may therefore argue that a contract for the transfer of human tissue and further processing of its data is a formal contract. If this is the case, then the absence of the form may lead to the nullity of the contract.

In the case of nullity of the contract because of contrariety to mandatory norms, public order or good morals an evident parallel exists with Article 5 C.C. that

prescribes that the acts of disposition of the own body are prohibited when they cause a permanent reduction of the person's physical integrity, or when they are otherwise contrary to law, public order or good morals. The prevailing Italian scholarly opinion considers that the legal categories of mandatory norms, public order and good morals do not exclusively pertain to the realm of contract law, but are legal categories that make reference to fundamental rights, including human dignity, or other constitutional principles or basic principles of the political and social order. In this regard, scholars and judges have used several principles embodied in constitutional norms to create a general normative framework that applies to the acts of disposition of the human body. This general normative framework includes Articles 2, 3, 13, 23 and 32 Cost. Furthermore, two general principles lie at the basis of this framework: the personalistic principle and the pluralistic principle. The interplay between these principles gives legitimacy to the societal objective of finding the maximum extension possible for the individual's capacity of self-determination, provided that the interests and rights of others are taken into account and adequately balanced with the ones of the person herself. Fundamental rights that are part of this constitutional framework could be applied directly or indirectly by Italian judges in cases involving contracts on human tissue. For this reason, the application of fundamental rights through the interpretation of open norms or general clauses of private law creates a virtuous circle whereby the content of these open norms is filled with constitutional principles and fundamental rights. In particular, the fundamental principle and supra-constitutional value of human dignity (embodied in Article 2 Cost.) may play a significant role in the determination of the validity of contracts on human tissue, especially in the assessment of the illegality of the cause or the object because of their contrariety to good morals.

With regards to the notion of physical integrity included in Article 5 C.C., the modern understanding of this notion brings it almost to the point of convergence to the notion of health embodied in Article 32 Cost. According to this view, the diminution of the person's physical integrity must be assessed by taking into account whether or not the act of disposition of the human body alters the relational life of the individual.

12.2 Validity of contracts on human tissue in the light of the supranational principle of prohibition of financial gain

Regarding the prohibition of financial gain – the general principle of international and EU law according to which the human body and its parts cannot be a source of financial gain – two different positions can be found in the Italian scholarly debate. According to a first position supported by Resta, there is a trend in European law towards the marginalization of market transaction on the human body and its parts. Resta derives the so-called extra-patrimoniality

principle from the wording of Article 3 subparagraph 2, lit. c CFREU and Article 21 of the Oviedo Convention. This principle, in Resta's view, has a twofold meaning. The first meaning revolves around the general rule of gratuitousness of the acts of disposition of the human body, which prohibits economic profit from the body, its parts and its functions, and constitutes the grounds for declaring void such transactions when concluded for economic profit. The second meaning entails that the human body and its parts cannot be the object of a patrimonial right.

According to a second position in Italian scholarly works, supported among others by Alpa and Ansaldo, the prohibitions embodied in the above mentioned supranational documents are only exceptions to the general rule of free disposition of the human body included in Article 5 C.C. In their view, when the detachment of the body part does not entail a permanent reduction of the person's physical integrity, the relation between the person and the part is one with patrimonial content and can be described in terms of the possibility of fruition and exchange.

Independently of the stance one takes on these two positions, the determination of the scope of application of the prohibition of financial gain under Italian law is difficult. Italian scholars have sustained that the prohibition included in the CFREU and the Oviedo Convention is limited to the fields of medicine and biology. Work contracts in the sports field, or for the commercial use of human body images or for prostitution are excluded from the prohibition of financial gain. Furthermore, this prohibition only refers to human body parts that have not been the object of transformation (e.g. fixing tissue samples in paraffin blocks). Finally, it would appear from the analysis of the Italian literature on the matter, that the prohibition of financial gain is limited to the relation between the first transferor and the first recipient of the tissue. The relations between the first and subsequent recipients are arguably not covered by this prohibition.

In the domain of the contracts for profit between the first transferor and the first recipient of human tissue, only a small number of contracts are explicitly allowed by Italian legislation: the transfer for profit of waste products and reproducible elements like teeth, hair and nails. The transfer for profit of human tissue for the purposes of scientific research and possible commercial uses thereof is not explicitly allowed nor explicitly prohibited. The debate on this matter is not entirely pacific in Italian scholarly literature, and Italian scholars have provided arguments in favour and against the validity of such transfers.

Several arguments have been advanced against the validity of contracts on human tissue for profit. From the point of view of the relation between the general prohibition of financial gain and the legal regime of the acts of disposition of the human body, it has been argued that the new legal regime of

the acts of disposition of the human body emerges from the interplay of the national and supranational legal sources that orbit around the paradigms of self-determination, solidarity, and gratuity. Since these paradigms are part of the modern understanding of the notion of public order (ex Article 1418 C.C), the transfer for profit of human tissue should be considered illegal because of its contrariety to public order. From the point of view of the relation of the prohibition of financial gain and human dignity, it has been argued that the conclusion of contracts on human tissue for profit risks the commodification of the human body, which is problematic from the perspective of the protection of the person's human dignity. From the perspective of the adequate protection of personal data, it has been argued that the transfer of human tissue and the data therein contained should be guided by the norms and set of principles on personal data and privacy. Since one of the main characteristics of these norms is the so-called paradigm of non-commercialization of data, the conclusion of contracts on human tissue for profit between the donor and the first recipient should be unlawful. Finally, from the viewpoint of delegating the collection of human tissue to the market it has been sustained that such delegation is inconvenient since the State (and not the market) is the one that should be the provider of health services in a system based on the logic of altruism and solidarity. Furthermore, delegating to the market the collection of human tissue would allegedly create a discriminatory effect among social classes whereby the sellers of human tissue in such markets would be the most economically disadvantaged individuals.

In favour of contracts on human tissue for profit, is has been sustained that such transfers do not represent a risk to the transferor's physical integrity and health, contrary to what happens, for example, with the donation of complete organs.

From the weighting of the above-described arguments against each other, one may argue that in Italian scholarly works there is a prevalent trend to not recognize the validity of contracts on human tissue for profit between the first transferor and the first recipient.

Finally, regarding the analysed MTA's several conclusions can be drawn. Firstly, there is a common core to both types of MTA's. This core includes the following characteristics: a) the prohibition of obtaining economic profit from the transferred materials; b) the necessity of obtaining consent from the providing institution for the transfer of the materials to a third party; c) the prohibition of using the transferred materials on humans and; d) the recognition of property rights on the materials. Secondly, it is noticeable how both contracts do not include any provisions regarding the consent of the original source of the materials or the protection of the data associated to the materials.

Part 4

ENGLAND & WALES

13

Chapter 13

Contracts on human tissue in the multi-level system of legal sources

PART 4 ENGLAND & WALES

CHAPTER 13 Contracts on human tissue in the multi-level system of legal sources

13.1 Overview of the relevant sources of law and regulation relevant for contracts on human tissue

The validity of contracts on human tissue in England & Wales is regulated by a multiplicity of legal sources at the national and supranational level.[537]

At the national level there is no statute specifically aimed at regulating contracts on human tissue, but from the interplay between statutory laws, common law, soft law and other regulatory arrangements, a possible legal framework for the regulation of these contracts can be distilled. The relevant sources of law and regulatory arrangements include:

1) The Human Tissue Act 2004 (hereafter, HTAct) that explicitly regulates the taking, storage and use of human tissue, [538]
2) The legislative debates on the HTAct relevant for the interpretation of the scope of its provisions,
3) The Human Rights Act 1998 that incorporates the ECHR into English law,[539]
4) The Data Protection Act 1998 and the GDPR,[540]
5) The common law doctrines on invalidity of contracts: illegality and public policy
6) The common law rules on the matters not explicitly regulated by statutory law (e.g. consent for the removal of human tissue),
7) The Human Tissue Authority (hereafter, HTA) Codes of Practice,[541]
8) Other non-binding ethical guidelines for the removal, use and storage of human tissue.[542]

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[537] For the international and supranational sources see Part 2 of this book.
[538] Human Tissue Act 2004, <http://www.legislation.gov.uk/ukpga/2004/30/contents> accessed 2 November 2019.
[539] Human Rights Act 1998, <http://www.legislation.gov.uk/ukpga/1998/42/contents> accessed 2 November 2019.
[540] On the GDPR see section 3.4. On the DPA 1998 see subsection 3.5.2.
[541] The Human Tissue Authority is a corporate body whose establishment was mandated by the HTAct. Among other functions, it has the preparation of codes of practice for the different activities within its remit.
[542] See for example the Guidelines of the Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues*, 1995 (thereafter NCB Guidelines 1995) <http://nuffieldbioethics.org/wp-content/uploads/2014/07/Human-tissue.pdf> accessed 2 April 2019; and the Guidelines of the Medical Research Council, *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines*, 2014 (thereafter MRC Guidelines 2014) <https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/> accessed 2 April 2019.

In order to analyse the relation between the aforementioned legal sources, the following Chapters are divided as following:

Chapter 14 addresses the legislative history, the relevant provisions and the normative framework of the HTAct, with particular reference to the notion of consent under the HTAct and the HTA Codes of Practice A (on the guiding principles and the guiding principle of consent) and E (on research). Chapter 15 analyses the requirements for consent in the matters not explicitly regulated by the HTAct, i.e. consent for the removal of human tissue from living persons. Chapter 16 provides an overview of the common law doctrines on the invalidity of contracts (illegality and public policy) and identifies some possible grounds that may impact the validity of contracts on human tissue. Chapter 17 is devoted to the effect of fundamental rights on private relationships under the law of England and Wales, with particular reference to the different theories on the horizontal effect of fundamental rights. Special attention is given in this Chapter to the relevance of the principle of human dignity to contemporary contract law and as a limit to the validity of contracts on human tissue. Chapter 18 analyses some examples and problems of the contractual practice on human tissue. Finally, Chapter 19 provides some concluding remarks on the validity of contracts on human tissue under the law of England and Wales.

14

Chapter 14

The Human Tissue Act 2004

CHAPTER 14 The Human Tissue Act 2004

14.1 Overview

In England, the HTAct is the main statutory law on the use and storage of human tissue. This chapter aims at providing a comprehensive overview of its provisions, with particular emphasis on those that are (directly or indirectly) relevant for the determination of the limits to the validity of contracts on human tissue. For this purpose, section 14.2 outlines the HTAct legislative history and section 14.3 analyses its regulatory aims. Section 14.4 draws some conclusions on the relevance of the HTAct for the validity of contracts on human tissue.

14.2 Legislative history

In the early 2000s the Kennedy Inquiry into infant cardiac surgery at Bristol Royal Infirmary[543] found out that dead infants' body parts had been retained for research purposes after post mortem examinations without the consent of their parents. Consequently, parents often buried their children unaware of the fact that some body parts were missing. The scandal grew for worse when the Redfern Inquiry[544] unveiled that the same practices had taken place at the Alder Hey Children´s hospital in Liverpool. Public attention on the matter increased even more after the Isaac report[545] revealed that even brains from mentally ill persons had been retained in other hospitals without the consent of the patients (or their legal representatives). The inquiries related to England and Wales, but similar practices occurred in Northern Ireland and Scotland. Furthermore, a census ordered by the Chief Medical Officer Professor Liam Donaldson discovered that more than 54,000 organs, foetuses, and body parts of children had been retained between 1970 and 1999 in England without proper consent.[546]

Although it was widely recognized that these practices were unacceptable, it also became evident that they were made possible by the legislation of the time. In fact, the legislation previous to the enactment of the HTAct 2004 authorized the person lawfully in possession of a dead body to remove and use parts of it for the

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[543] The Bristol Royal Infirmary Inquiry (2000) Interim Report - Removal and retention of human material , available at http://www.bristol-inquiry.org.uk.

[544] The Royal Liverpool Children's Inquiry (2000) Report, available at http://www.rlcinquiry.org.uk/index.htm).

[545] Issac Report, HM Inspector of anatomy, the investigation of events that followed the death of Cyril Mark Isaac, May 2003, available at <http://image.guardian.co.uk/sys-files/Society/documents/2003/05/12/isaacs_report.pdf> last accessed 2 December 2019.

[546] Report of a Census of Organs and Tissue in the Retained by Pathology Services in England (London: DOH, 2001, available at http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065088.pdf, <last accessed 16 December 2019>. On this matter see also Hoppe and Miola, 2014, p. 212.

purposes of therapy, education and research where there was no evidence of any objections from the relatives.[547] In addition to the shortcomings of the previous legislation, another cause of the scandal consisted in that it was a common belief among hospitals and physicians that the retention of organs was important for the development of science and that asking consent to the parents would bring further grieve to the already suffering relatives.[548] Furthermore, for pathologists and clinicians, human materials were regarded as mere objects.[549]

The shortcomings of the existing legislation on human tissue and organ transplants[550] were already pointed out by scholarly literature,[551] which also argued for an urgent legislative reform. Such reform followed in 2004, with the enactment of the Human Tissue Act 2004.

On the one hand, the HTAct 2004 was as a response to the scandals and practices reported in the Bristol and Liverpool Inquiries and an attempt to remedy the failures of the previous normative framework. On the other hand, the HTAct 2004 is also the United's Kingdom implementation of the Tissue and Cells Directive 2004.[552]

14.3 The Act's rules on the use of human tissue

14.3.1 Preliminary remarks

According to paragraph 4 of the Explanatory Notes to the HTAct 2004, the Act's aim is threefold.[553] Firstly, it "provides a consistent framework for issues relating to whole body donation and taking, storage and use of human organs and tissue". Secondly, it "makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons". Finally, it "intends to provide a balance between the right and expectations of individuals and families, and broader consideration such as the importance of research, education, training, pathology and public health surveillance to the population as a whole".

The structure of this section mirrors these three different aims. Firstly, subsection 14.3.2 describes the activities governed by the HTAct and the Act's general normative framework. Secondly, subsection 14.3.3 focuses on consent as

[547] In particular, the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organs Transplants Act 1989.
[548] Herring, 2014, p. 415: "The views of the hospitals involved were described in the Kennedy Report as 'institutional paternalism'".
[549] See fn. 543.
[550] See fn. 547.
[551] Price, 2003, p. 1 with further references.
[552] On this Directive see fn. 462.
[553] Explanatory Notes to the Human Tissue Act 2004, para 4. <http://www.legislation.gov.uk/ukpga/2004/30/notes/contents> accessed 2 November 2019.

regulated by the HTAct and HTA's Code of Practice A[554] and E[555]. Thirdly, subsection 14.3.4 analyses those provisions of the HTAct that restrict activities on human tissue because they may bear relevance for the balancing of the rights and interests of the various societal stakeholders and for the determination of the limits of the validity of contracts on human tissue.

14.3.2 General normative framework of the HTAct

Section 1(1)-(3) of the HTAct lists the different activities that can be lawfully performed with appropriate consent:[556] (1) the storage and use of bodies of deceased persons; (2) the removal, storage and use of any relevant material which comes from bodies of a deceased person; and (3) the storage and use of relevant material which comes from bodies of living persons.

Relevant material in the sense of the HTAct means material, other than gametes, which consists of or includes human cells (with the exception of embryos outside the human body, or hair and nails from the body of a living person).[557] According to the HTA Code of Practice E, "(t)he fundamental concept of relevant material is that if a samples is known to contain even a single cell that has come from a human body, then the sample should be classified as relevant material."[558]

The HTAct definition of relevant material has raised some criticism among scholars. Firstly, because it is not clear why the relevant material only can consist or include human cells[559] since the human body also consists of non-cellular or other animals or bacterial material.[560] Secondly, because a distinction should have been made between a sample and organs or other large pieces of material since the requirements for consent when dealing with organs could

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[554] Human Tissue Authority, *Code of Practice A: Guiding Principles and the Fundamental Principle of Consent*, Human Tissue Authority 2017 <https://www.hta.gov.uk/sites/default/files/files/HTA%20Code%20A.pdf> accessed 2 November 2019. (Hereafter HTA Code of Practice A).

[555] Human Tissue Authority, *Code of Practice E: Research*, Human Tissue Authority 2017 <https://www.hta.gov.uk/sites/default/files/Code%20E%20-%20Research%20Final.pdf> accessed 2 November 2019. (Hereafter HTA Code of Practice E).

[556] Human Tissue Act 2004, s1(1)-(3).

[557] Human Tissue Act 2004, s 53: "(1) In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells. (2) In this Act, references to relevant material from a human body do not include- (a)embryos outside the human body, or (b) hair and nail from the body of a living person."

[558] Code of Practice E, para 27.

[559] Price, 2005, p. 801: "Moreover, Part 2 of Schedule 1 sets out various purposes for which consent will not normally be required vis a vis tissue taken from the *living* (at the point of removal) persons, namely clinic audit, education and training relating to human health, public health monitoring, quality assurance and performance assessments"

[560] Herring 2014, p. 431.

differ from the ones for, for example, placing a small amount of tissue on a slide.[561]

14.3.3 Consent under the HTAct and the HTA Codes of Practice A and E

Part 1 of Schedule 1 of the HTAct lists the purposes for which it will be necessary to obtain consent when carrying on the three types of activities mentioned in section 14.3.2 above. These purposes are:

1. Anatomical examination;
2. Determining the cause of death;
3. Establishing after a person's death the efficacy of any drug or other treatment administered to him;
4. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
5. Public display;
6. Research in connection with disorders, or the functioning, of the human body;
7. Transplantation.

The HTAct 2004 does not deal with other purposes that might be given to human tissue, e.g. their use in an art project or for prurience.[562]

Part 2 of Schedule 1 lists the purposes for which consent is not required when using or storing material from a deceased person:

1. Clinical audit;
2. Educational or training relating to human health;
3. Performance assessment;
4. Public health monitoring and quality assurance.

Sections 1(4)(9) of the HTAct creates a series of exceptions to the requirement of consent in the activities described in sections 1(1)-(3) of the same statute. Consent is not needed:

1. When the body or the relevant materials come from a person who died at least 100 years before these sections of the Act come into force.
2. When the body or the relevant materials have been imported.
3. For the use and storage of relevant material that comes from a *living* person for the purpose of research in connection with disorders or the functioning of the human body provided that: "(a) it is ethically approved in accordance with regulations made by the Secretary of State and; (b) it

[561] Ibid.
[562] Herring, 2011, p. 179.

> is to be, or is, carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the person from whose body the material has come can be identified".[563]

For what concerns the first exception, it clearly aims at excluding the archaeological specimens within the consent provisions.[564] However, the second and third exceptions raise some difficulties.

The second exception was intended to allow the import of bodies and relevant material from countries where the material was lawfully collected without consent (i.e. the U.S.). However, certain scenarios can be imagined where material is imported without meeting the legal[565] and ethical standards required by English law and governance.[566] For this reason, the HTA considers it a good practice "for there to me mechanism in place to provide assurance that the tissue has been obtained with valid consent".[567]

Furthermore, subsection (13)[568] of the HTAct excludes from this exception the bodies or materials that have been exported with the purpose of being re-imported in order to circumvent the consent requirements.

The third exception was included because of the fear of many researchers, physicians and politicians[569] that research would be seriously affected[570] if consent was required in relation to surplus tissue originally obtained for other purposes.[571] In fact, during the parliamentary debates on the Human Tissue Bill, MP Andrew Lansley stated: "My difficulty is that the term ''explicit consent'' as it has developed in common law is intended to reflect the fact that someone had a particular purpose in mind when giving consent. Unless it is clear that storage for use for a purpose might mean adaptation to meet other purposes, which could not have been contemplated when consent was given, there is a risk that one may have to return to the original donor to satisfy the consent requirements. That could be very onerous".

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[563] Human Tissue Act 2004, s 1(9).
[564] Explanatory Notes to the Human Tissue Act 2004, para 12.
[565] The issue was debated in parliament but no further provisions were included on this matter on the argument that the guidelines on this matter should be dealt with by the Human Tissue Authority. Human Tissue Bill Deb, 27 January 2004, col 48.
[566] A similar problem occurred in the case of the famous exhibition "Bodies" in France, which was banned by the Cour de Cassation because of serious doubts on the legal origin of the bodies. It was believed they came from Chinese prisoners sentenced to the capital punishment. See Cour de Cassation, Chambre Civil 1, 16 Septembre 2010.
[567] Code of Practice E para. 62.
[568] Human Tissue Act 2004, s 1 (13): "In this section, the references to a body or material which has been imported after do not include a body or material which has been imported after having been exported with a view to its subsequently being re-imported".
[569] Human Tissue Bill Deb, 27 January 2004, col 48.
[570] McHale, 2010, p. 1013
[571] Price, 2005, p. 803.

In order to prevent the hampering of research and protect at the same time the personal data of the person from whom the tissue was obtained, the third exception prescribes that the tissue must be unlinked from the personal information of the source of the material. However it is not necessary that the material becomes irreversibly anonymized. During the discussion of the Bill the minister of State at the Department of Health said that anonymization would "not mean that the patient and the tissue would be permanently unlinked. Further information could be sought from the records, but the researcher should not get identifying information, and the ethics committees would be able to consider what arrangements were appropriate in each case".[572] It can be assumed therefore that the corresponding provisions of the HTAct make reference to the so-called codification process.[573]

In this regard, the Code of Practice E provides two examples of cases when tissue originally collected for other purposes can be used in research:

Example A: "A researcher wishes to use paraffin-embedded blocks of surgically removed thyroid tissue stored in the archives of a pathology department after its use for diagnosis. As consent for the use of their tissue for research was not originally sought from the patient, it can only be released from the diagnostic archive if it does not identify the patient and is used in a specific project that has been approved by a recognised REC."[574]

Example B: "A researcher requires whole blood for a research project. She is able to access blood samples from a diagnostic archive in a hospital biochemistry laboratory, which have been stored for the intended purpose of diagnosis and screening. Consent for the use of the samples for research was not obtained. The researcher can use these samples without the patients' consent, provided the samples are not identifiable to her and the specific project has been approved by a recognised REC."[575]

In relation to the requirement of ethical approval included in the aforementioned third exception to the requirement of consent, the Code of Practice E further specifies that "Ethical approval which qualifies for exemption under the HTAct can only be given by a recognized REC, which is either: a) a REC recognised or established by, or on behalf of, the HRA under the Care Act 2014 or any other group of persons which assesses the ethics of research involving individuals and which is recognized for that purpose by, or on behalf of, the Welsh Ministers if

[572] Human Tissue Bill Deb, 28 June 2004, col 97. https://publications.parliament.uk/pa/cm200304/cmhansrd/vo040628/debtext/40628-31.htm> accessed 2 November 2019.
[573] Codification is a process consisting in the attribution of a code to the tissue simple so the identity of the original source of the simple remains unknown to the researchers.
[574] Code of Practice E, para 30.
[575] Code of Practice E, para 30.

the Department of Health in Northern Ireland; or b) an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA) to review clinical trials of investigational medicinal products under the Medicines for Human Use (clinical Trials) Regulations 2004."[576]

However, according to the Code of Practice E, a university ethics committee does not qualify, for the purposes of the aforementioned consent exception, as a recognised REC. In the cases where university ethics committees are involved, consent will always be required.[577]

-*Consent under Codes of Practice A and E*

With certain exceptions, the whole normative body of the HTAct is essentially built on the notion of consent.[578] However, the HTAct does not define consent. It merely indicates that certain activities shall be considered lawful if carried on with appropriate consent.[579] For this reason, to understand the scope of the notion of consent under the HTAct references to the Human Tissue Authority (HTA) Code of Practice A – which is entirely devoted to the issue of consent – and Code of Practice E on research, are necessary.

The Code of Practice A, together with other sector specific codes, aims at providing guidance to anyone undertaking activities relevant to each sector (e.g. research) on the minimum steps to comply with the legislation on human tissue.[580] This Code is divided in three sections. Section One sets out four guiding principles, which are derived from the HTAct: a) consent; b) dignity; c) quality; and d) honesty and openness. Section Two explains the importance of consent and Section Three is intended to provide guidance on the statutory requirements for consent.[581]

Section One lists the content of each of the four guiding principles. Regarding *consent* it states: "Consent and the wishes of the donor (…) have primacy when removing, storing and using human tissue. This means: a) human tissue (…) should be used in accordance with the expressed wished of donors (…) b) donors and their relatives should be given the information they need to be able to make a decision that is right for them (…).[582] Regarding *dignity*, the following content is particularly relevant for the determination of the validity of contracts on human tissue: "a) the dignity of the donor should be respected of all times; (…) c) the privacy of the individual should be maintained and (…); f) where human tissue is imported, importers should endeavour to ensure that it is sourced from a

[576] Code of Practice E, para 65.
[577] Code of Practice E, para 68.
[578] Miola, 2010, p. 81.
[579] McHale, 2010, p. 1016.
[580] Code of Practice A, para. 9.
[581] Code of Practice A, para. 8, 9 and 10.
[582] Code of Practice A, para. 12.

country that has an appropriate ethical and legal framework.[583] Regarding the principles of *quality* and *honesty* and *openness*, the Code of Practice A indicates that they should, respectively, underpin the management of human tissue and should be the foundation of communications in matters pertaining the use of human tissue.[584]

According to the HTA Code of Practice A, consent is necessary for storing and using material from the living.[585] Although obtaining consent is not a legal requirement for the disposal, this Code indicates that it is a good practice for disposal option to be provided, and to obtain consent for them.

The HTAct qualifies the term consent by indicating that it has to be appropriate.[586] Appropriate consent is to be understood in terms of the person who may give consent,[587] or in other words, it has to be given by the person entitled to consent: in the case of living adults consent means the one of the donor.[588]

Furthermore, in order for consent to be valid it must be given voluntarily by a person with the capacity to agree and understand the activities and risks involved.[589] In this regard, the Code of Practice A puts forward the following test of materiality: "whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach a significance to it".[590]

The form of expression of consent is irrelevant for its validity unless the HTAct requires it to be in writing. It is recommended to record it, when possible.[591]

The HTA Code of Practice A notes that: "Consent may be specific or it may be broader in its scope, sometimes referred to as 'generic consent'. Specific consent is given in relation to a defined project, treatment and/or use. Generic consent refers to a broader permission, where consent may, for example, be given to allow the storage and use of tissue for an as yet unknown research project. In practical terms, specific and generic consent may be sought at the same time, to derive the greatest benefit from valuable human tissue donated for research."[592]

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[583] Code of Practice A, para. 13.
[584] Code of Practice A, para. 14 and 15.
[585] Code of Practice A, para 26.
[586] Human Tissue Act 2004 s 1(1). The following activities shall be done with *appropriate* consent (…). Code of Practice A, para 40.
[587] Code of Practice A, para 18.
[588] Hoppe & Miola, 2014, p. 215.
[589] Code of Practice A, para 40.
[590] Code of Practice A, para 40.
[591] Code of Practice A, para 44.
[592] Code of Practice A, para 41.

Similarly to the HTA Code of Practice A, Lord Warner commented in the House of Lords on behalf of the government: "Let me state clearly that the Bill does not require consent to be specific to each research project for which tissue might be used. Consent can be broad. Consent to research can be generic and enduring".[593]

According to the Code of Practice A, it is possible for the person to place limits on their consent. An individual could, for example, limit her consent to a particular type of research, or for a certain amount of time.[594]

The possibility of setting conditions to the use of tissue is relevant for the determination of the limits to the validity of contracts. In fact, according to the Code of Practice A, it would be an offence to carry an activity for a scheduled purpose, in the knowledge that the person has attached a condition to consent that does not allow for the use of her tissue for that particular activity.[595] Such condition would entail the inexistence of valid consent for that particular activity.

Regarding the withdrawal of consent, Code of Practice A prescribes that consent can be withdrawn at any time. A person can withdraw her consent for all purposes, or just for a specific scheduled purpose. When consent remains in place for other purposes, the tissue can continue to be used for those purposes. In any case, the information and research data extracted from the tissue before the withdrawal of consent can still be used in the project for which the person originally consented. For obvious reason, the person cannot withdraw her consent when the tissue has already been entirely consumed.[596]

Section Three of the Code of Practice A refers to the statutory requirements of consent. Particularly relevant for the purposes of this book are the requirements of human tissue from living persons therein included. However, since the removal of human tissue from the living is governed by common law, and not by the HTAct, the analysis of such requirements will be done in the separate Chapter 15 below specifically devoted to the requirements of consent under common law.

The Code of Practice E on research provides further guidance on the requirements of consent for the use of tissue in research. In particular, this Code specifies that, for the purposes of transparency, when research is likely to involve the commercial sector, or genetic testing, or it is likely that the sample will be exported abroad, it would be desirable that this information is provided to support the consent process of the individual.[597]

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[593] HL Deb 22 July 2004, vol 664, col 370.
[594] Code of Practice A, para 45 and 50.
[595] Code of Practice A, para 48.
[596] Code of Practice A, para 51 and 52.
[597] Code of Practice E, para. 49.

Finally, although the Codes of Practice are not strictly legally binding, the Code of Practice A prescribes the following: "Establishments are expected to follow the guidance contained in the Codes. Observance of the guidance is one of the ways the HTA assesses that establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HTAct, but the HTA will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action".[598] However, the HTA does not licence the use of tissue for research, nor does it have a role in the ethical approval of research projects. The HTA's role in research is restricted to licensing premises for the storage of tissue from the living and the deceased.[599] For this reason, the HTA does not have a stake in the determination of the validity of contracts on human tissue.

14.3.4 Restrictions of activities in relation to donated material and the prohibition of commercial dealings in human materials for transplantation

The HTAct included two types of restrictions of activities on human tissue. The first type of restriction is included in section 8(1) of the HTAct which prescribes that a person commits an offence if she uses or stores donated material for a purpose other than a qualifying purpose.

Qualifying purposes are:[600]

a) Those specified in Schedule 1 Part 1 of the HTAct.
b) Medical diagnosis or treatment.
c) Decent disposal.
d) A purpose specified in regulations made by the Secretary of State.

According to section 8(6) "(…) a material is subject of donation if authority under section 1 (1) to (3) exist in relation to it", or in other words, if it is a material to be used for: the storage and use of bodies of deceased persons; the removal, storage and use of any relevant material which comes from bodies of a deceased persons; and (3) the storage and use of relevant material which comes from bodies of living persons.

Furthermore, when a person reasonably believes that what she uses or stores is not donated material[601] the person does not commit an offence, or in the words of the Explanatory Notes to the HTAct 2004: "the offence will not apply where a

[598] Code of Practice A, Annex A, para. 13.
[599] Code of Practice E, para 10 and 11.
[600] Section 8(a) HTAct.
[601] Section 8(6) specifies that a body or a material, is the subject of donation if authority under section 1(1) to (3) exists in relation to it.

person believes on reasonable grounds that the body or material is not relevant material which is the subject of appropriate consent".[602]

The second type of restriction is embodied in section 32 of the HTAct. This section refers to the general prohibition of commercial dealings in human material for transplantation. According to section 32(1) a person commits an offence if he:

a) Gives or receives a reward for the supply of, or for an offer to supply, any controlled material;
b) Seeks to find a person willing to supply any controlled material for reward;
c) Offers to supply any controlled material for reward;
d) Initiates or negotiated any arrangements involving the giving of a reward for the supply of, or for an offer to supply, any controlled material;
e) Takes part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.[603]

Section 32(2) states that "a person commits an offence if he causes to be published or distributed, or knowingly publishes or distributed, or knowingly publishes or distributes, an advertisement -

a) inviting persons to supply, or offering to supply, any controlled material for rewards, or
b) indicating that the advertiser is willing to initiate or negotiate any such arrangement(…)".

The definition of controlled material is given by the HTAct itself in subsection 32(8): it is any material that (a) consists of or includes human cells, (b) is, or is intended to be removed, from a human body, (c) is intended to be used for the purpose of transplantation, and (d) is not a kind excepted under subsection (9), i.e. gametes, embryos, and material which is the subject of property because of an application of human skill.[604] Cell lines are also excluded according to section 54(7), as any other material created outside the body.

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[602] Explanatory Notes to the Human Tissue Act 2004, para 25.
[603] The situations described in b) and e) seems to be directed to control the cases of brokering for human body materials. See for example: http://www.forbes.com/forbes/2007/0129/072.html
[604] English law seems to consider the application of human skill an exception to the so-called no property rule on the human body. The first precedent on this matter comes from the famous Australian case, Doodeward v. Spence (1908) 6 CLR 406, in which a two-headed foetus was preserved in a bottle of spirits. In this case, Justice Griffiths CJ argued that: "When a person has by the lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it." For further case law on the matter

The term 'reward' was included to designate any kind of material advantage so the law could not be bypassed by offering in exchange of the material goods different than cash. However, the prohibition of commercial dealings is not as strict as it might first appear. On the one hand, the prohibition is only limited to material destined to transplantation. On the other hand, section 32(6) specifies that: "for the purposes of sections 32(1) and (2), payment in money or money's worth to the holder of a license shall be treated as not being a reward where –

a) it is in consideration for transporting, removing, preparing, preserving or storing controlled material, and,
b) its receipt by the holder of the license is not expressly prohibited by the terms of the license.

Section 16(2) of the HTAct 2004 lists the activities that require a license, including the storage of relevant material which has come from a human body for a schedule purpose.

Section 17 of the HTAct 2004 specifies that the authority conferred by the license applies to: "a) the designated individual, b) any person who is designated as a person to whom a license applies by a notice given to the Authority by the designated individual, and any person acting under the direction of - (i) the designated individual, or (ii) a person designated as mentioned in paragraph (b)."

The HTAct also includes in subsection 32(3) an exception to the prohibition of commercial dealings: a person does not commit any of the offences if he is designated by the HTA to engage in these activities. The National Blood service, for example, could be permitted to buy blood from abroad.[605]

Finally, the Code of practice E further specifies that "Research tissue banks may charge for providing human tissue samples to researchers, including those working for private companies, so that their running costs are recovered and the viability of the bank is maintained. Where cost recovery, or any other charging mechanism, is in place it is important that research tissue banks are able to satisfy themselves that the information provided to potential donors is sufficient to ensure they understand that their tissue may be shared, subject to a fee being charged. The HTA also recommends that research tissue banks ensure transparency by providing easily accessible information about how and why they charge, and to whom they will supply tissue samples. This is important to

see: Dobson v. North Tyneside Health Authority and another [1997] 1WLR 596. For scholarly literature on the exceptions to the no-property rule see: Taylor, 2002.
[605] Herring, 2014, p. 455.

ensure that the consent sought from donors to the research tissue bank is fully informed."[606]

14.4 Concluding remarks on the validity of contracts on human tissue under the HTA

This chapter's tripartite analysis of the provision of the HTAct is useful to determine which provisions may apply to the determination of the validity of contracts on human tissue.

Firstly, for what concerns human tissues from living persons, the HTAct 2004 only regulates its storage and use. The removal of human tissue from living persons remains outside the scope of the HTACT and is governed by common law.[607]

Secondly, the requirement of consent only applies to the use and storage from living persons for the purposes listed in Part 1 of Schedule 1 of the HTAct 2004. From that list, one may argue that only the following purposes bear relevance for contracts on human tissue: obtaining scientific or medical information about a living person which may be relevant to any other person (including a future person); public display; and research in connection with disorders, or the functioning, of the human body. Other purposes such as the use of human tissue in an artwork, or for prurience are not within the scope of the HTAct.

Thirdly, the HTAct only prohibits commercial dealings on material destined to transplantation. Any other purpose (e.g. research) seems to be excluded from the prohibition of the HTAct.

From these considerations the following questions arise: 1) How is consent for the removal of human tissue regulated under common law? 2) What is the regulation of contracts on human tissue for purposes different than the ones listed in Part 1 Schedule 1 of the HTAct 2004, e.g. the use of these materials for artistic works? 3) Is it possible under English law to engage in commercial dealings on human tissue for purposes different than transplantation?

Arguably, the answer to the second and third question lies in the common law doctrines of illegality and public policy. Chapter 16 will explore these doctrines.

The following chapter on consent under common law aims at answering the first question.

[606] Code of Practice E, para. 49.
[607] Price, 2005, p. 801.

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Chapter 15

Consent for the removal of tissue from living persons in England & Wales

CHAPTER 15 Consent for the removal of tissue from living persons in England & Wales

15.1. Overview

The HTAct regulates consent for the use and storage of human tissue from living persons but it does not regulate consent for medical treatment and examination. This matter is regulated by common law. Paragraph 39 of the Code of Practice E (on research) specifies that "(a)lthough the HTAct deals with the removal of tissue from the deceased, consent to treatment and examination (and the removal of tissue from living for research) is covered by the common law and the Mental Capacity Act (MCAct) 2005 where appropriate (…). Trusts should have local policies in place for seeking consent to treatment and the legal position is set out in the Department of Health's guidance". The aforementioned guidance is included in the Department of Health reference guide to consent for examination or treatment (hereafter, DH guide to consent).[608] Similarly, paragraph 113 of the Code of Practice A indicates that the MCAct outlines the criteria to apply in order to determine whether an adult has the capacity to consent for the removal of tissue.

For this reason, the removal of tissue from living persons has to comply both with the rules laid down in these guidelines and with the rules of common law for consent. The following section outlines these rules.

15.2 Consent for the removal of tissue from living persons under common law

Under English law there is no specific statute setting out the principles of consent for medical treatment and examination, but common law has developed tests and rules to determine the existence and validity of consent. These rules stem from the principles of autonomy and self-determination.[609] There seems to be consensus on the fact that the legal and ethical legal principle of consent reflects the right of the persons to decide what happens to their own bodies[610] and the right to keep one's own whole body intact.[611] Personal autonomy is protected by granting the individual a sphere of control over her own body: the

[608] Department of Health, Reference guide for examination or treatment, Second Edition, 2009, available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf last accessed 16 December 2019.
[609] For case law see on these principles see: Schloendorff v. Society of New York Hospital (1914) 105 N.E. 92; S v. McC; W v.W [1972] AC 24, 43; Nancy B v. Hotel-Dieu de Quebec (1992) 86 DLR; Airedale NHS Trust v. Bland [1993] A.C. 789
[610] See for example the DH guide to consent p. 5; Hockton, 2002, p. 9.
[611] See also Re A (conjoined twins) [2001] 2 WLR 480.

right to bodily integrity.[612] When a breach of consent occurs, the right to bodily integrity is also violated and the actor of the violation might be liable in tort law [613] for battery [614] and, under certain circumstances, for the tort of negligence.[615] Battery has been defined as an intentional and unjustified act that causes direct contact with the claimant's body.[616] Legal liability in negligence requires three elements: the existence of a duty of care, a breach of that duty; and a legally recognised damage arising from the breach of that duty.[617]

According to the DH guide to consent, "(f)or consent to be valid, it must be given voluntarily by an appropriate informed person who has the capacity to consent to the intervention in question (…) Acquiescence where the person does not know what the intervention entails is not 'consent'".[618] From this definition the following elements can be identified in order to determine the validity of consent: capacity, voluntariness and appropriate information. The Mental Capacity Act 2005 provides the definition of a person lacking capacity.[619] The need of voluntariness has for long been a requirement in the common law.[620] To determine whether consent has been given voluntarily, account must be given to the question of whether pressure or undue influence has been exerted on the person. [621] Finally, a person has received sufficient information when she understands the nature and purpose of the procedure. This information is sufficient to consider consent as valid in relation to any claims of battery, but this is not sufficient to fulfil the legal duty of care to a person.[622]

The starting point on negligence and the issue of consent and the duty to inform patients can be traced to the House of Lords' *Sidaway* decision.[623] There is considerable divergence in the scholarly interpretations of *Sidaway*.[624] The DH guide to consent takes position on the different scholarly interpretations and provides its own understanding of the case. It states that "the legal standard to be used when deciding whether adequate information had been given to a patient should be the same as that used when judging whether a doctor had been negligent in their treatment or care of a patient: a doctor would not be

[612] Maclean, 2009, p. 150
[613] For scholarly works on the torts of battery and negligence see: Cooke, 2015; Horsey & Rackley, 2015; Markesinis & Deakin, 2013; Lunney & Oliphant; 2013; McBride & Bagshaw, 2013.
[614] Maclean, 2009, p. 150; Hockton, 2002, p.13.
[615] DH guide to consent, 2009, p. 5
[616] Trinidade, 1982, p. 211 cited in Maclean, 2009, p. 150.
[617] Maclean, 2009, p. 162.
[618] DH guide to consent, 2009, p. 9
[619] See Part 1 Mental Capacity Act 2005
[620] Re T [1992]; Freeman v the Home Office (No 2) [1984].
[621] DH guide to consent, 2009, p. 11.
[622] Ibid, p. 12.
[623] Sidaway v. Governors of Bethlam Royal Hospital [1985] AC 871
[624] See Maclean, 2009, p. 167 with further reference.

considered negligent if their practice conformed to that of a responsible body of medical opinion held by practitioners skilled in the field in question."[625]

Later, in *Chester v Afshar*,[626] the House of Lords ruled that "(a) surgeon owes a general duty to a patient to warn him or her in general terms of possible serious risks involved in the procedure. The only qualification is that there may be wholly exceptional cases where objectively in the best interests of the patient the surgeon may be excused from giving a warning... In modern law medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small, but well-established, risk of serious injury as a result of surgery." From this case it can be derived that a person seeking to remove human tissue from another should always explain to him/her all possible risks associated to the procedure.

The most recent version of the Medical Research Council's Operational and Ethical Guidelines on Human tissue and biological samples for use in research (hereafter MRC guidelines)[627] and the General Medical Council guidelines on good practice in research and consent to research (hereafter GMC guidelines)[628] provide further rules on the consent requirements for research. According to the MRC guidelines, the information provided to the donors of the material should include: the risks associated to the procedure, what the samples will be used for, how the results of the research might impact the donor's interests, and the intention of future storage and use of the samples.[629] The GMC guidelines further specify that people must be informed of their right to decline to take part in research or to withdraw from the research project at any time.[630]

However, according to the Health Research Authority, when consent from the living is given to remove tissue for diagnostic and therapeutic purposes, if the tissue is also intended to be used and stored for research "it is good practice to seek specific consent for research at the same time but it is not a legal requirement. Tissue from the living may be stored and used for research without consent provided the research is ethically approved and the researcher cannot identify the donors".[631]

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[625] DH guide to consent, p. 12.
[626] Chester v Afshar [2004] UKHL 41.
[627] MRC, 2014 available at: https://www.mrc.ac.uk/publications/browse/human-tissue-and-biological-samples-for-use-in-research/ Last accessed: 19th April 2019
[628] GMC, 2013 available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-research/annex-a-legal-and-governance-framework last accessed: 19 April 2019.
[629] MRC, 2014, p. 10,
[630] GMC guidelines, para. 29.
[631] Health Research Authority, at http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-the-human-tissue-act-2004/. Last accessed 16 December 2017.

Last, but not least, the DH guide to consent[632] stresses the importance of the compliance with the Human Rights Act 1998 (HRA 1998) in the existing ethical practice. According to these guidelines, health practitioners should be aware of the HRA 1998 and public bodies should act in a manner compatible with the Convention rights unless an act of parliament makes that impossible.
According to these guidelines, the most relevant articles of the HTA 1998 for medical case law are Articles 2, 3, 8, 9, 10, 12 and 14. The implication of the HRA 1998 for contracts on human tissue will be discussed in detail in Chapter 17.

15.3 Concluding remarks on the effect of the doctrine of consent on the validity of contracts on human tissue

Although the HTAct regulates the issue of consent for the use and storage of human tissue from living persons, it does not regulate consent for the removal of tissue from the living for the purposes of medical treatment, examination or research. However, under common law, consent is always required for the removal of tissue from living persons.
According to the Code of Practice E on research (paragraph 41), the legal position for obtaining consent for treatment is set out in the DH guide to consent.
For these reasons, the legal regime on consent for the removal of tissue from the living can be found in the common law rules on consent understood in the light of the aforementioned guidance.
In what concerns the common law rules, when a breach of consent occurs, the person violating the right to bodily integrity may be liable under the torts of battery or negligence.[633]
The presence of three elements is necessary to determine the validity of consent:[634] capacity, voluntariness and appropriate information. The Mental Capacity Act 2005 already provides a definition of a person's lacking capacity. To assess whether or not consent has been given voluntarily it is necessary to determine whether undue influence or coercion has been exercised on the person. Finally, it is considered that a person has received appropriate information when she understands the nature and purpose of the procedure.[635]
The fulfilment of the requirement of appropriate information suffices to consider consent as valid and precludes the claims under the tort of battery but it is not sufficient in regards to the legal duty of care towards a person under the tort of negligence. Two cases are particularly important in relation to the issue of consent and the duty to inform: the House of Lords' *Sidaway* and *Chester v Afshar*.[636] From the former case it can be derived that the standard to decide whether appropriate information has been given should be the same as when

[632] DH guide to consent, 2009, p. 6.
[633] See fn. 613 above.
[634] On this see 15.2 above.
[635] Ibid.
[636] See fn. 626 above.

judging whether or not a doctor has acted with negligence, that is, a doctor should not be considered liable if her practice conformed to the medical opinion of a responsible body of skilled practitioners. From the latter case, it can be derived that a person seeking to remove human tissue must always explain all the risk associated to the procedure at stake.

Moreover, according to the MRC guidelines, the information that must be given to the source of the tissue must include –besides the risks associated to the procedure– the purposes for which the tissue samples will be used, how the results of the research may impact the person's interest, and the possible intentions for future use and storage of the samples. The GMC guidelines further specify that the person must be informed on their right to decline taking part in the research or to withdraw from the research at any time.

Finally, the DH guide is emphatic in the importance of the compliance with the HRA 1998 in medical practice.[637]

From the aforementioned general considerations on the issue of consent under common law, the following consequences for the validity of contracts may be derived: a contract for the use of human tissue in research that entails the removal of human tissue from a living person must comply with the requirements for the taking of consent under common law and under the medical and ethical guidelines described in this Chapter. Particularly relevant are the requirements of capacity, voluntariness and appropriate information. One may argue that if one of these requirements is missing –aside from the possible existence of a tort of battery or negligence– the contract should also be considered invalid. The concrete grounds for the invalidity of the contract will be explored in the following Chapter.

[637] See fn. 632 above.

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Chapter 16

Common law doctrines on the invalidity of contracts

CHAPTER 16 Common law doctrines on the invalidity of contracts

16.1 Overview

This chapter provides an overview of the common law doctrines of illegality and public policy insofar as relevant for the validity of contracts on human tissue. It will firstly refer to the scholarly taxonomy of illegality (section 16.2). Secondly, this Chapter will address the general characteristics of the public policy doctrine (section 16.3). Thirdly, it will identify the headings of illegality and/or public policy that could possibly constitute limitations to the validity of contracts on human tissue with particular reference to the relevant provisions of the HTAct and the common law doctrine of consent (section 16.4).

16.2 Illegality

The common law doctrines of illegality and public policy have often been described as complex[638] and notoriously difficult.[639] In fact, English courts and legal literature have dealt with these doctrines in many different ways and depending on the consulted scholar a different classification of illegal contracts can be found:

(1) Edwin Peel in *Treitel: The Law of Contract* (henceforth, *Treitel*)[640] divides the contracts affected by illegality in two general categories: 'Contracts involving the commission of a legal wrong' and 'contracts contrary to public policy'. The former includes contracts: (i) amounting to a legal wrong, (ii) to commit a crime, (iii) to commit a civil wrong, (iv) which are in themselves lawful but are used for an unlawful purpose, and (v) in which the method of performance is unlawful. The latter category (contracts contrary to public policy) comprises an heterogeneous group of contracts:[641] (i) agreements by married persons to marry, (ii) agreements in contemplation of divorce, (iii) agreements inconsistent with parental responsibility, (iv) agreements in restraint of marriage, (v) marriage brokerage contracts, (vi) contracts promoting sexual immorality, (vii) contracts interfering with the course of justice, (viii) contracts purporting to oust the jurisdiction of the courts, (ix) contracts to deceive public authorities, (x) sale of offices and honours, (xi) lobbying and bribery, (xii) trading with the enemy, (xiii) contracts which involve doing an illegal act in a friendly foreign country, (xiv) contracts restricting personal liberty, and finally, (xv) contracts in restraint of trade, which is given an entire separate section.

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[638] Beatson, Burrows, Cartwright, 2010, p. 379.
[639] Elliott & Quinn, 2013, p. 253.
[640] Treitel, 2011, p. 470.
[641] Ibid. p. 488-501.

(2) H.G. Beale, W.D. Bishop and M.P. Furmston follow a similar classification:[642] (i) contracts contrary to public policy and (ii) contracts involving the commission of a crime or tort. The contracts in restraint of trade, while being categorized under the heading of contracts against public policy are dealt with separately because they are the most frequently litigated and developed.[643]

(3) *Anson's Law of Contract*[644] (henceforth, *Anson*) proposes a classification of illegal contracts based on the kind of law breached by the contract: statutory law or common law. On the one hand a contract is illegal if either its conclusion or its performance is expressly or implicitly prohibited by statute. On the other hand a contract is illegal if it is contrary to public policy under common law.[645] Under the category of contracts contrary to public policy, the following types of contracts are contained: (i) agreements to commit a crime or civil wrong, or to perpetrate a fraud, (ii) agreements which injure the state in its relations with other states, (iii) agreements which tend to injure good government, (iv) agreements which tend to pervert the course of justice, (v) agreements which are contrary to good morals,[646] (vi) agreements which affect the freedom or security of marriage or the due discharge of parental duty, (vii) agreements which oust the jurisdiction of the courts, and (viii) agreements in restraint of trade.

(4) Other authors (e.g. D.D Prentice in *Chitty on Contracts*, [647] follow classifications that are more or less similar to the above-mentioned three taxonomies. Therefore, these further classifications will not be described in detail here.

Because different headings of illegality or public policy might prove useful for the analysis of contracts on human tissue, this book follows a combined taxonomy with the most relevant headings proposed by *Treitel* and *Anson*'s (see Section 16.4).

16.3 Public policy

The common law doctrine of public policy is usually framed within the broader common law doctrine of illegality.[648] The notion of public policy is of the

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[642] Ibid, p. 1069.
[643] Ibid, p.1073.
[644] Beatson, Burrows, Cartwright, 2010, p. 379.
[645] Ibid, p. 384.
[646] *Anson* is one of the few books to include agreements contrary to good morals as an example of illegality at common law. However, it makes clear that 'Although it has sometimes been said that contracts *contra bonos mores*- contrary to good morals- are void, the only aspect of immorality with which Courts of law have actually dealt is sexual immorality'. Ibid. p. 393.
[647] Beale, 2012, p. 1223.
[648] Mansoor, 2014, p. 13.

foremost importance for the analysis of the validity of contracts because this notion, as Waddams has convincingly argued,[649] "(…) might plausibly be presented as a primary, or even a threshold requirement for the creation of enforceable obligations."[650]

However, there is no uncontroverted definition of public policy in English contract law. Since a detailed analysis of the characteristics and content of this notion would exceed the purposes of the present book, this section will merely provide a summary of the current state of the literature and case law on the topic.

Public policy is a variable notion. The scope that the courts and scholars have given to it has changed during time. In the late eighteen-century and the beginning of the nineteenth, it was considered that the content of contracts should not only be possible to be accomplished but should also respect the principles of morality and sound policy. However, in the course of the nineteenth century the concept of public policy turned to be considered as 'a very unruly horse (…) when once you get astride it you never know where it will carry you'.[651] As a consequence, commentators and judges restricted the cases in which a contract shall be unenforceable by reasons of public policy. The view was expressed that the courts' function[652] was to interpret the existing law and to protect the principle of freedom of contract because of the public interest invested on it.[653]

However, by the second half of the twentieth century, the active role of the courts in matters related to public policy was increasingly, but cautiously, recognized.[654] Nowadays it seems that courts are looking for a balance between public policy and contractual certainty.

Modern scholars have attempted to define public policy.[655] Independently of the differences in the definitions, some general characteristics can be outlined. It is a flexible notion that changes depending on socioeconomic and political conditions, the development of public opinion and the public sense of morality.

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[649] Waddams, 2011, p. 148.
[650] Ibid.
[651] *Richardson v. Mellish* (1824) 2 Bing 229, 252, per Burrough J. Cited in Waddams, 2011, p. 153
[652] Lord Halsbury denied the courts the possibility of invent a new head of public policy'. *Janson v Driefontain Consolidated Mines ltd*. 1902 Cited in Treitel, 2011, p. 486.
[653] 'The effect of the nineteenth century emphasis on freedom of contract was reluctance to interfere with a contact on the ground of public policy'. In '*Anson*', 2010, p. 384
[654] On the cautious acceptance of the active role of courts in English law see Mansoor, 2014, p. 23-
[655] 'Public policy is a variable notion, depending on changing manners, morals and economic conditions. In theory, this flexibility of the doctrine of public policy could provide a judge with an excuse invalidating any contract which he violently disliked'. Treitel, p. 486. 'The application of canons of public policy to particular instances necessarily varies with the progressive development of the public opinion and morality, but like any other branch of the law is governed by the judicial use of the precedents. Anson, 2010, p. 384.

In certain situations it can be the sole ground for judges to consider a contract as unenforceable,[656] void or illegal.[657] Public policy is essentially a doctrine for the protection of public interests rather than a doctrine concerned with the fairness of the contract as between parties to a dispute,[658] notwithstanding the fact that sometimes the protection of the individual rights of one contracting party constitutes a prevailing public interest.

16.4 Headings of illegality or public policy that possibly limit the validity of contracts on human tissue

One may argue that seven headings of illegality or public policy proposed by *Treitel* and/or *Anson*'s constitute limitations to the validity of contracts on human tissue: (1) contracts amounting to a legal wrong,[659] (2) contracts to commit a crime, (3) contracts to commit a civil wrong or perpetrate a fraud, (4) agreements which are in themselves lawful but are used for an unlawful purpose, (5) agreements in which the method of performance is unlawful, (6) contracts restricting personal liberty, and (7) contracts contrary to good morals. The following paragraphs will discuss each of these headings with reference to possible examples of illegal contracts on human tissue.

(1) *Contracts amounting to a legal wrong*

A contract is illegal if the fact of just concluding it amounts to a legal wrong, for example if it is expressly or implicitly prohibited by statute.[660]

Section 32 of the HTAct prohibits commercial dealings in human material for transplantation. More specifically, section 32(1) prescribes, among other things that a person commits an offence if she a) gives or receives a reward for the supply of, or for an offer to supply any controlled material; b) seeks to find a person willing to supply any controlled material for reward; c) offers to supply any controlled material for reward; d) initiates or negotiates any arrangements involving the giving of a reward for the supply of, or for the offer to supply, any controlled material; e) takes part in the management or control of a body of persons corporate or unincorporated whose activities consist of or include the initiation or negotiations of such arrangement.

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[656] "There are some contracts that are considered to be so inimical to the interest of the public (…) that they should not be enforced." Beale, Bishop, Furmston, 2008, p. 1069.

[657] Some authors prefer the use of the term illegality over to describe those situation in which the rights of the contracts are denied for being contrary to public policy or because a statutory prohibition. Anson, 2010, p. 379.

[658] Hounga v Allen & Anor [2014] IKSC 47 para 56.

[659] This research understands 'contracts amounting to a legal wrong' in the same sense it is understood by Treitel, 2011, p. 474.

[660] Treitel, 2011, p. 474; see also Beatson, Burrows, Cartwright, 2010, p. 379

Furthermore, section 32(2) states that a person commits an offence if she causes to be published or distributed, or knowingly publishes or distributes, an advertising – a) inviting persons to supply, or offering to supply, any controlled material for reward, or b) indicating that the advertiser is willing to initiate or negotiate any such arrangement.

One may argue that some of the activities listed in section 32 (1)-(2) of the HTAct (i.e. 32(1)-(a)-(b)-(d)-(e) and 32(2)) constitute contracts on human tissue that are expressly prohibited by statue and therefore tainted with illegality. Furthermore, all of the activities listed under 32(1)-(2) are also offences and fall under the category of contracts to commit a crime.

(2) Contracts to commit a crime

A contract for the commission of a crime is obviously illegal and Courts will not enforce such an agreement. A clear example would be the engaging in the activities described in section 32 of the HTAct 2004.[661]

Furthermore, section 8(1) of the HTAct 2004 prescribes that a person commits an offence if she uses or stores donated material for a purpose different than a qualifying purpose.[662] As a consequence, if contracts on human tissue have within their scope the use or storage of donated material for an unqualified purpose then the contract ought to be considered as illegal, e.g. a contract would be illegal if its purpose is to use in an art installation human tissue that was originally donated for the purposes of research.

(3) *Contracts to commit a civil wrong or perpetrate a fraud*

A contract is illegal if its purpose is the deliberate commission of a civil wrong, in other words, if it is intended to serve to the commission of a tort or other unlawful act against another person or their property.[663] Because the valid consent of the person is, in most cases, a necessary requirement for the use of human tissue, one may argue that contracts on human tissue between institutions could be tainted with illegality if, for example, they are deliberately

[661] Section 32(4) of the HTAct 2004 states that a person guilty of an offence under section 32(1) shall be liable of (a) on summary conviction – (i) to imprisonment for a term not exceeding 12 months or (ii) to a fine not exceeding the stator maximum, or to (iii) both; (b) on conviction on indictment – (i) to imprisonment for a term not exceeding 3 year or (ii) to a fine, or to (iii) both. Similarly, section 32(5) prescribes that a person guilty of an offence under section 32(2) shall be liable of (a) on summary conviction – (a) to imprisonment for a term not exceeding 51 weeks or (b) to a fine not exceeding level 5 on the standard scale, or to (c) both.

[662] See subsection 14.3.4.

[663] The Black's law dictionary defines civil wrong as: An action with a tort, an act against another person or their property, and, a breach of the terms of a contract. http://thelawdictionary.org/civil-wrong/

used to circumvent the requirement of valid consent given by the original donor for the use of her tissue.[664]

(4) *Agreements which are in themselves lawful but are used for an unlawful purpose*

A contract is illegal if one of the parties knows that the other party intends to use the contract for an unlawful purpose. If for example, in a contract on human tissue one of the parties knows that research will be carried out on tissue without the necessary legal requirements for it (e.g. approval from the research ethical committee), that should be considered, prima facie, as illegal.

(5) *Agreements in which the method of performance is unlawful*

According to Section 4(1)5 lit. (a) of the HTAct, a person commits an offence if "he has any bodily material intending (i) that any human DNA in the material be analysed without qualifying consent, and (ii) that the result of the analyses be used otherwise than for an excepted purpose." From this provision it follows that a contract to analyse the DNA contained in human tissue is not *per se* illegal, but it becomes illegal if the performance (i.e. the analysis of the DNA) is done without qualifying consent.

(6) *Contracts restricting personal liberty*

According to *Treitel* "a contract may be illegal if it so severely restricts the liberty of an individual as to reduce him to a quasi-servile condition".[665] One may question, however, whether only contracts reducing individuals to a quasi-servile condition can be considered contrary to public policy under the present heading. Indeed, it is possible to imagine scenarios where a contract severely restricts personal liberty without bringing the person to such an extreme condition. Some have argued that research on identified human tissue may be considered a form of experimentation on humans.[666] From this it could be inferred that a contract on these materials would be illegal if it restricts the possibility of the donor of withdrawing at any time her consent for the research.[667] One may argue that the donor's personal liberty would be hampered if she is not allowed to withdraw the consent to use her tissue for a research study where this material could be linked to her personal data. In this case, the limitation of personal liberty would arguably be of the same quality as in the case where a research participant is not allowed to withdraw her consent to be object of a study involving experimentation on humans.

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[664] See subsection 14.3.3.
[665] Treitel, 2011, p. 501.
[666] Tallacchini, 2005, p. 158.
[667] On the necessity of allowing withdrawal of consent at any time see fn. 596 above.

(7) *Immoral contracts*

English courts have dealt with the issue of illegality on the grounds of contravening good morals only in relation with sexual immorality.[1] However, given the particular sensitive nature of the matter of contracts on human tissue it is possible to imagine different scenarios where good morals could play a role in deciding the legality of such contracts. The question of whether it is possible for a person to transfer her human tissue for research in exchange of a fee has revolved around the problem of whether it is moral to give economic value to a human body part. A contract stipulating such an exchange may be challenged in its legality on the grounds of immorality.

16.5 Concluding remarks on the validity of contracts on human tissue under common law

This Chapter identified seven headings of illegality and public policy that could constitute grounds for challenging the validity of contracts on human tissue: contracts amounting to a legal wrong, contracts to commit a crime, contract to commit a civil wrong or perpetrate fraud, agreements which are in themselves lawful but are used for an unlawful purpose, agreements in which the method of performance is unlawful, contracts restricting personal liberty, and contract contrary to good morals.

In particular, these seven headings are relevant for at least four aspects of the subject matter of this book. First, for the determination of the limits to the validity of contracts on human tissue stemming from statutory sources, as in the cases of contracts amounting to a legal wrong and contracts to commit a crime in relation to the normative provisions of the HTAct (e.g. section 32 HTAct). Second, for the analysis of other relevant legal sources that complement the legal regime on the removal, use and storage of human tissue, and in particular for the analysis of the contracts to commit a civil wrong or perpetrate fraud in relation to the legal regime of consent under common law.[2] Third, for the assessment of the validity of contracts on human tissue when the purposes of the contract are not explicitly or implicitly regulated by law (e.g. the use of human tissue for artwork). Fourth, for the role that the notion of good morals may play when deciding the validity of contracts with a highly disputed moral content (e.g. contracts for the sale of human tissue).

[1] On the relation between public policy and good morals see Mansoor, 2016. For case law see for example: AVB vs TDD [2013] EWHC 1705 (QB)
[2] See Chapter 15.

Finally, the examples brought forward in this Chapter in relation to the different headings of illegality or public policy do not constitute an exhaustive list of possible cases of invalidity of contracts on human tissue, but are only a way to indicate possible outcome(s) of the interplay between the multi-level system of sources of law and governance.

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Chapter 17

Fundamental rights and their effect on private relationships in England & Wales

CHAPTER 17 Fundamental rights and their effect on private relationships in England & Wales

17.1 Overview

The coming into force of the HRA 1998 in 2000, which incorporates the ECHR rights into UK law,[670] caused (a still ongoing) debate about the effects of fundamental rights on private relationships.[671] For this reason, Section 17.2 provides a brief overview of the relation between private law and fundamental rights under the law of England & Wales.[672] Section 17.3 identifies the different terminological uses of the terms 'horizontal effect', 'direct horizontal effect' and 'indirect horizontal effect'. Section 17.4 briefly outlines the different theories on the horizontal effect of fundamental rights in the law of England & Wales. Section 17.5 assesses the relevance of the principle of human dignity under the law of England & Wales in general, and contract law in particular.[673] Finally, section 17.6 provides some concluding remarks on the effect of fundamental rights in the validity of contracts on human tissue.

17.2 The relationship between private law and fundamental rights under the law of England & Wales

Three particular features of the legal system of England & Wales make the analysis of the effects of fundamental rights on private relationships in this legal system different from the analysis of the same phenomenon in other European countries.[674] The first feature is the absence of a written constitution adopted by Parliament.[675] The second feature is that the law of England & Wales has been traditionally a liberties based system,[676] rather than one founded on rights. As a consequence, the domestication of the rights included in the ECHR meant a shift from a liberties based structure towards a rights based one.[677] The third feature is the lack of a sharp distinction between public and private law.[678]

Collins explains the possible structural relations between public and private law with the metaphor of the building of houses.[679] According to a first view reported

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[670] See fn. 24.
[671] See for instance: Hunt, 1998; Wade, 1998; Phillipson, 1999; Wade 2000, Bamforth, 2001; Young, 2007; Young 2014; Young 2014 (1); Krahé 2015.
[672] For a study on the influence of EU and European human rights law on English private law, see Giliker, 2015, p. 237.
[673] On the impact of human rights on English Contract Law see Du Bois, 2017, p. 1.
[674] For a comparative study see Brüggemeier, Colombi Ciacchi and Comandé (Eds), 2010. On the relationship between the UK and European Human Rights see: Wicks, Ziegler and Hodson, 2016.
[675] Youngs, 2016, p. 559; Oliver, 2007, p. 63; Mak, 2008, p. 22.
[676] Gajdosova & Zehetner, 2010, p. 122; Mak, 2008, p. 23; Oliver, 2007, 63.
[677] Cherednychenko , 2007, p. 136.
[678] Cherednychenko, 2007, p. 120. See also, Gajdosova and Zehetner, 2010, p. 188.
[679] Collins, 2014, p. 37.

on by Collins, private law and constitutional law are like two semi-detached houses that support each other but are inhabited separately. In developing private law, lawyers should make sure that it does not violate constitutional values. In the same way, lawyers should make sure that public law does not interfere with the normal processes of private law. This interpretation has been labelled by Collins the mutual support structure. According to a second view, private law could be seen as a "detailed articulation of constitutional rights"[680] because constitutional laws and principles are the foundations on which both private and public law are built upon. Collins called this view the single source structure.[681] According to him, this structure would encourage the direct effect of fundamental rights between private parties.[682]

The following sections will explore in which direction are scholars and courts heading with regards to the articulating of the relationship between private law and public law, and in particular between human rights and contract law.

17.3 Terminological uses of the terms 'horizontal effect', 'direct horizontal effect' and 'indirect horizontal effect'

Before the HRA 1998, which incorporated into domestic law the rights comprised in the ECHR,[683] acts of parliament and the common law provided the legal protection for the liberties of individuals against the State and other private parties. Many acts of parliament provided special protection to dignity and autonomy of vulnerable parties in private relationships (e.g. employment statutes, family law and marriage laws, and children's legislation).[684] Scholars have argued that already before the HRA 1998, courts had been influenced by the rights incorporated in the Convention in interpreting statutes or the common law.[685]

However, the scholarly discussion about the horizontal effect of fundamental rights in England is more recent than in other European countries. On the one hand, English scholars have been traditionally reluctant to embrace the idea of human rights as a source of 'positive' legal obligations, prioritizing instead 'negative' obligations embodied in the concept of liberties.[686] On the other hand, in other European countries (such as Germany, Italy, or the Netherlands), the debate on the horizontal effect of fundamental rights arose in the 1940s-1950s in relation to the horizontal effects of national constitutional provisions. No similar debate could arise in the UK because of the absence of a written constitution. For

[680] Ibid, p. 37.
[681] Collins, 2011, p. 133.
[682] Collins, 2014, p. 37. Collins however does not support the direct horizontal effect theory.
[683] Cherednychenko , 2007, p. 120; Baele and Pittam, 2001, 131.
[684] Oliver, 2007, p. 64.
[685] Giliker, 2014, p. 12 with further reference.
[686] Gajdosova and Zehetner, 2010, p. 119.

these reasons, the debate on the horizontal effect of fundamental rights started in the UK only after the enactment of the HRA 1998.

The text of the HRA 1998 is not explicit in determining the extent of the effect of fundamental rights on private relationships. Article 3(1) regarding the interpretation of legislation prescribes that "(s)o far as it is possible to do so, primary legislation and subordinate legislation must be read and given effect in a way which is compatible with the Convention rights". Moreover, according to Article 6(1) "it is unlawful for a public authority to act in a way which is incompatible with a Convention right".

Article 6(1) raises the question of what should be understood as a public authority. According to Article 6(3) public authority is "any person certain of whose functions are of a public nature". Scholars have thereof drawn the conclusion that mixed function bodies (private and public) count as public authorities when exercising their public function.[687]

While it is clear from the wording of article 3(1) that legislation will have to be consistent with the ECHR, significant doubts on the role of fundamental rights in disputes between private parties ruled by common law still remain.[688] The following section explores the different theories on the effect of Convention rights on private relationships under English law.

17.4 Models of the horizontal effect of Convention rights

Regarding the effect of Convention rights on private law relationships, the discussion in England & Wales has mostly focused on whether or not Convention rights – as incorporated by the HRA 1998 – should have direct or indirect effect on relationships between private actors. Direct horizontality takes place when a private individual can invoke a Convention right directly before a court.[689] Indirect horizontality consists in giving effect to a Convention right through the interpretation and application of a different rule or doctrine already existent in the common law.[690]

Two main arguments have been brought forward to support the direct effect of ECHR rights: a literal argument and an argument based on the spirit of the Convention. The first argument is based on sections 6(1) and 6(3) of the HRA 1998. Some scholars have proposed that courts should always give weight to the rights of the ECHR, independently of the nature of the persons involved in the dispute, because the HRA 1998 makes it unlawful for a public authority to act

[687] Baele & Pittam, 2001, p. 31.
[688] Gajdosova and Zehetner, 2010, p. 122.
[689] Young, 2007, p. 38.
[690] Ibid, p. 39.

incompatibly with a Convention right and section 6(3)[691] includes courts and tribunals in the definition of public authorities.[692]

The second argument is that, even though the original purpose of the ECHR was to protect the citizen from the abuses of State power, nowadays the citizens can legitimately expect respect for their rights from both private actors and the State.[693]

Against the direct horizontal effect, it has been said that the HRA 1998 does not directly incorporate the Convention rights into English law but courts are obliged to read and give effect to legislation in a way that is compatible to the Convention.[694] Furthermore, it has been said that the horizontal effect of the Convention and the principle of *Drittwirkung*[695] are based on article 1 ECHR, and since Article 1 ECHR was not incorporated by the HRA 1998, it would appear that the parliamentary intention was not to give direct horizontal effect to the rights therein incorporated. A similar conclusion has been drawn from the absence of the Article 13 ECHR (on right to an effective remedy) in the HRA 1998.[696]

Regarding the indirect effect of Convention rights, scholarly literature has traditionally distinguished between strong and week indirect horizontal effect. In general terms, according to the strong indirect effect model, courts must ensure the compatibility of all existing law with the ECHR, placing the compatibility analysis on the rights invoked and not only on the values behind these rights.[697] This view is strongly supported by Hunt[698] on the basis of his analysis of the text of the HRA 1998, the White Paper which accompanied the Bill and the reports of the parliamentary debates on the Bill. According to Hunt, "one of the effects of making courts and tribunals public authorities in clause 6 of the HRA 1998[699] is not merely to impose the same obligation on courts and tribunals in relation to the common law, but to impose a duty on them to act compatibly with the law, including in purely private disputes between the parties."[700] According to this view even though courts have the duty to give preference to the rights embodied in the ECHR over the private common law, they are not allowed

[691] "In this section "public authority" includes- (a) a court or tribunal, and (b) any person certain of whose functions are functions of a public nature, (…)"Article 6 HRA 1998.
[692] Wade, 2000, p. 218. For a discussion of Wade's approach see Mak, 2008, p. 120 and O. Cherednychenko, 2007, p. 141.
[693] Wade, 2000, p. 224. Cf. Cherednychenko, 2007, p. 125.
[694] Young, 2007, p. 47 with further references.
[695] See 316 above.
[696] Young, 2007, p. 47 with further references.
[697] J. Gajdosova and J. Zehetner, 2010, p. 153.
[698] Hunt, 1998, p. 177.
[699] 6(1) It is unlawful for a public authority to act in a way which is incompatible with a Convention right.¨ 6(3) In this section public authority¨ includes (a) a court or tribunal¨.
[700] Hunt, 1998, p. 177. See also Baele & Pittam, 2001, p. 137.

to create entirely new causes of action.[701] As a result, one of the foreseeable consequences of this approach is that the existing causes of action may have to change and adapt in order to satisfy the demands that the protection of fundamental rights between private parties entails.[702]

According to the weak indirect effect model, courts should consider the *values* and *principles*[703] represented in the ECHR at the moment of solving the disputes between private parties. Courts should consider these *values* to apply and develop existing law and to adjudicate disputes between private parties. However, they do not have an absolute duty to attain the conformity of common law with the ECHR *rights*. A natural consequence of this line of argumentation is that the relation between private common law and human rights is one of complementarity and not of subordination.[704]

However, according to Alison Young, "the distinction between strong and weak horizontality glosses over some of the subtle differences between the different models of horizontality found in the academic literature".[705] For this reason, she identifies a wider variety of models of the possible indirect horizontal effect of Convention rights:[706] (a) the "negative obligation model" according to which courts are not obliged nor empowered to develop common law consistently with the Convention, but are however required to not contravene Convention rights when developing common law; (b) the "weak indirect horizontality model" according to which the courts have the *power* to develop common law in line with the values of the Convention; (c) the "strong/weak indirect horizontality" which combines elements of the traditional strong and weak indirect horizontality models and *obliges* the courts to develop common law compatibly with the values underpinning the Convention; (d) the "limited strong horizontality model" according to which courts can only incrementally develop common law to protect Convention rights; (e) the "strong indirect horizontality + no new cause of action model" in which Courts, in developing common law compatibly with Convention rights, cannot create new causes of action; (f) the "strong indirect horizontality + incremental new causes of action model" in

[701] Cherednychenko, 2007, p. 141.
[702] Hunt, 1998, p. 180.
[703] Gajdosova and Zehetner, 2010, p. 153: "Weak indirect horizontality is (…) the form in which courts may and ought to attempt to develop the common law in light of, and in a way that is consistent with, constitutional rights and values.
[704] Cherednychenko, 2007, p. 145.
[705] Young, 2007, p. 39.
[706] Young, 2007, p. 39-41. Other scholars have proposed different models that in general terms comprehend the models proposed by Young. See for example Cherednychenko, 2007, p. 124-129, who distinguishes between a) Direct horizontal effect; b) Strong indirect horizontal effect; c) weak indirect horizontal effect; d) No horizontal effect (or only vertical effect). See also Hunt, 1998, p.159, who distinguishes between: a) vertical effect (no effect); b) direct horizontal effect; c) indirect horizontal effect and d) application to all law (comparable to the strong indirect horizontal effect). See also Beale & Pittam, 2001, p. 132, who distinguish between direct horizontal effect, strong indirect horizontal effect and weak indirect horizontal effect.

which the creation of new causes of action is possible when compatibly developing common law with Convention rights and; (g) the "unlimited strong horizontality model" in which there are no limits for the courts to develop common law compatibly with Convention rights.

Finally, some scholars have also argued for a model that only recognizes vertical effect to the Convention. Two main arguments have been brought forward to support this view. The first argument indicates that fundamental rights have only vertical effect because their scope of protection ought to be limited to the relations with the State or public powers.[707] This view stems from classical liberalism and implies that the range of action for the pursuit of the person's own interest should be broadened as much as possible without undue interferences. According to the second argument the scope of protection of the rights embodied in the ECHR cannot be changed when incorporating them into English law. Since the European Court of Human Rights only deals with claims against States, also the HRA can only grant rights vis-à-vis public powers.[708]

From the position of courts and commentators in England & Wales there seems to be consensus on the exclusion of the direct horizontal effect.[709] It has been argued that the HRA 1998 supports a model of indirect horizontal effect, but it remains unclear from the wording of the HRA which of the different models of indirect effect should be preferred.[710] It would appear from the case law[711] and literature[712] that the developments in this field will tend towards the indirect horizontal effect in one of its weaker versions, leading to a relation of complementarity between private law and fundamental rights,[713] to ensure that existing private law rules and doctrines can be given new interpretations in the light of fundamental rights.[714] In this line of reasoning, Giliker has argued that "(i)ndirect horizontal effect presents English courts, therefore, with an opportunity to utilize Convention rights as a springboard for change. While this would further increase the divide between common law jurisdictions, it would move the English common law closer to a Convention-based framework of rights. It would, however, require the English courts to utilize European, not common law, analogies in the development of domestic private law".[715]

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[707] This argument is described by Hunt, but he actually pleads for the strong indirect horizontal effect theory. See M. Hunt, 1998, p. 160.
[708] Buxton 2000. Cf. Mak, 2008, p. 121.
[709] Brownsword, 2001, p. 181. Cf. Wade, 2000.
[710] Young, 2007, p. 48; Krahé, 2015, p. 150.
[711] See also Douglas v Hello! Ltd [2005] EWCA Civ 595.
[712] Phillipson, 1999; Beale and Pittam, 2001, p. 137; Young, 2007.
[713] Cherednychenko, 2007, p. 160.
[714] Cherednychenko, 2007, p. 141.
[715] Giliker, 2015, p. 249.

Two English cases in particular provide a strong argument against the direct horizontal effect of Convention rights:[716] *Wainwright v Home Office*[717] and *Campbell v MGN Ltd*.[718] In the first case, the House of Lords denied both the existence of a right to privacy in English law and the necessity of creating one. In the second case, the House of Lords gave a new interpretation to the common law doctrine of breach of confidentiality, by taking into account Article 8 and Article 10 ECHR. According to some scholars, if the intention of article 6(3) would have been to grant horizontal effect, then the House of Lords in *Wainwright v Home Office* would have been obliged to incorporate article 8 ECHR (on privacy) into English law.[719] The *Wainwright v Home Office* decision was reinforced in *Campbell v MGN Ltd* when Baroness Hale argued that "(t)he 1998 Act does not create any new causes of action between private persons".[720]

17.5 Human dignity

17.5.1 Preliminary remarks

According to a widespread view in English legal literature, with the domestication[721] of the rights contained in the ECHR, English courts must at minimum, ensure the compatibility of the common law with these rights. However, from the wording of the HRA 1998 or the ECHR it cannot be automatically concluded that human dignity plays a role as a limitation to the validity of contracts. In fact, human dignity is not explicitly mentioned in the ECHR or the HRA. Therefore, the question arises of whether or not the principle of respect for human dignity is relevant to the contemporary law of England & Wales in general and contract law in particular.

17.5.2 Is the principle of human dignity relevant to contemporary contract law in England & Wales?

Traditionally, English law has been reluctant to grant remedies for the infringements on human dignity. However, one may argue that under contemporary English law human dignity is an interest capable and worthy of protection.[722] As Beyleveld and Brownsword observe, "human dignity is the infrastructure on which the modern superstructure of human rights is constructed".[723]

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[716] Young, 2007, p. 41
[717] Wainwright v Home Office [2003] UKHL 53
[718] Campbell v MGN Ltd [2004] UKHL 22
[719] Young, 2007, p. 41.
[720] Campbell v MGN Ltd [2004] UKHL 22 para 132.
[721] Cherednychenko, 2007, p. 120 with further reference. See also section 17.4.
[722] Hardcastle, 2007, p. 175.
[723] Beyleveld and Brownsword, 2001, p. 210

Despite the fact that the notion of human dignity is not explicitly mentioned in the text of the ECHR, there seems to be a wide consensus on that the ECHR includes in its catalogue of rights the principles agreed on in the Universal Declaration on Human Rights,[724] in which human dignity is declared as one of its pivotal ideas. Furthermore, interpretations of the European Commission and the ECtHR have relied extensively on the concept of human dignity for their decisions on cases involving the right to physical integrity,[725] the right to a fair hearing,[726] the right to not to be punished in the absence of a legal prohibition,[727] the right to private life,[728] and the prohibition of torture.[729] In fact, the ECtHR has sustained that "the very essence of the Convention is respect for Human Dignity and human freedom".[730]

Section 2(1)(a) of the HRA 1998 requires English courts to take into account the relevant case law of the ECtHR when determining a question related to a right included in the ECHR. In fact, English Courts have not only taken into account the relevant case law of the ECtHR, but have also gradually made use of the principle of human dignity in their decisions. Lord Millet held in *Rees v Darlington memorial Hospital NHS Trust*[731] that human dignity "(…) is increasingly being regarded as an important human right which should be protected by law."[732] In the same line of reasoning he argued in *McFarlane v Tayside Health*[733] that 'autonomy can be viewed as an aspect of human dignity and that the protection of autonomy can also be viewed as the protection of human dignity'. In the *Limbuela* case,[734] the Nationality, Immigration, and Asylum Act was challenged on the grounds that it diminished the human dignity of the claimants (asylum seekers) and violated article 3 of the ECHR (on the prohibition of torture). Lord Craighead argued in this case that "(w)here treatment humiliates or debases and individual showing a lack of respect for, or diminishing, his or her human dignity… it may be characterized as degrading and also fall within the prohibition of article 3".[735]

Therefore, one may argue then that even if not explicitly mentioned in the text of the ECHR and the HRA 1998, the principle of human dignity is enshrined in both legal documents and is thus relevant for English law. In the words of

[724] See fn. 23 above.
[725] Tyrer v United Kingdsom, 2 EHRR 1, para. 33.
[726] Bock v Germany, 12 ECRR (1990) 247, para 48.
[727] SW v. UK; CR v. UK, 21 EHRR (1995) 363, para 44.
[728] Von Hannover v Germany 40 EHRR (2004)1; Goodwin v. United Kingdom, 35 EHRR (2002) 447, para. 90-91.
[729] Ribitisch v. Austria, 21 EHRR (1995) 573, para. 38.
[730] Pretty v. United Kingdom, 24 EHRR (1997) 423, para 65.
[731] Rees v Darlington memorial Hospital NHS Trust [2003] UKHL 52
[732] Ibid. Para 123.
[733] McFarlane v Tayside Health, [1999] UKHL 50.
[734] R. v Secretary of State for the Home Dept., exparte Limbuela [2005] UKHL 66 (HL).
[735] Ibid. Para 76.

Brownsword: "(…) unless one stands on an extreme literalism, it is difficult to resist the proposition that respect for human dignity is the implicit foundation of the Human Right Act".[736]

The idea of human dignity playing a role in English contract law may seem to many English lawyers as implausible. In fact, it is difficult, if not impossible, to find a court decision using the notion of human dignity for the adjudication of disputes as between private parties. However, a significant decision of the Supreme Court of Israel[737] may bring some light for a possible use of the principle of human dignity in disputes between private parties in common law jurisdictions. In the case '*Jerusalem Community' Funeral Society v. Lionel Aryet Kesterbaum* the respondent contracted with a funeral society for the funeral arrangements of his wife. The respondent wife's will, indicated that her tombstone should have her name in Latin characters and her date of birth and death etched according to the Gregorian calendar. The terms of the standard contract signed by both parties indicated that the inscription on the tombstone could only include the letters of the Hebrew alphabet. On these grounds the funeral society refused to engrave the tombstone. In a split decision, the majority of the court decided that the contract was void because it violated the human dignity and the rights to freedom of expression and conscience of the respondent. Even though this case has not been broadly discussed by English scholars,[738] it illustrates the use that the notion of human dignity can play in common law based legal systems.

Moreover, the role of human dignity in English contract law can be derived by the role of other human rights in contract law. As has been argued by some,[739] in order for human dignity to be functional, it needs other notions that are usually presented using the terminology of rights: "the practical business of pressing one´s interests against others is conducted in terms of claimed human rights".[740]

Finally, the idea that the principle of dignity may play a role in the limits to the use of human tissue seems to be confirmed by the fact that the HTA Code of Practice A on Consent considers dignity as one of the four guiding principles for the use of human tissue.[741] According to this Code, "(d)ignity should be paramount in the treatment of human tissue and bodies. This means: a) the dignity of the donor should be respected at all times; b) there should be mechanisms in place to protect bodies and human organs and tissue from harm;

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[736] Brownsword, 2001, p. 188 with further references.
[737] Israeli legal system is mainly based on common law.
[738] For the relevance of this case in English law see Beyleveld & Brownsword, 2001, p. 206; Brownsword, 2001, p.182. For a broader discussion on the case see for example: Marella, 2008, p. 127.
[739] Andorno, 2009, p. 234.
[740] Beyleveld and Brownsword, 2001, p. 13.
[741] On the Code of Practice A see subsection 14.3.3.

c) the privacy of the individual should be maintained; d) the disposal of human tissue should be managed sensitively and the method of disposal should be appropriate to the nature of the material; e) disposal of human tissue from the deceased should, where possible, be in line with their wishes, if known, or the wishes of the deceased person's relatives; f) where human tissue is imported, importers should endeavour to ensure that it is sourced from a country that has an appropriate ethical and legal framework."[742]

17.6 Concluding remarks on the effect of fundamental rights on the validity of contracts on human tissue

From the analysis of the horizontal effect of fundamental rights under English law it can be distilled that the human rights enshrined in the HRA have at least an indirect horizontal effect among private parties and could constitute (indirect) limits to the validity of contracts on human tissue.

With regard to the relationship between English contract law and human rights, it has been argued that, in many occasions, the reasons for courts declaring contracts void resemble the protection of a human right, for example in the cases of contracts restraining personal liberty or freedom of speech.[743] Some scholars have also maintained that contractual provisions should arguably be interpreted in a way that makes them compatible with the Convention rights and that when a contract cannot be interpreted in such a manner, it should be considered unenforceable on the ground of its contrariety to public policy. [744] This view seems to me confirmed by Youngs, according to whom, "(it) has been expressed that invalidation of contracts for breaches of ECHR rights in general would be an appropriate step."[745]

Finally, regarding principle of human dignity, it is possible to reasonably argue that it may play a role in the determination of the limits to the validity of contracts. Firstly, the ECHR -and therefore also the HRA 1998- includes in its catalogues of rights the principles of the Universal Declaration of Human Rights, in which human dignity plays an essential part.[746] Secondly, English courts are obliged, according to Section 2(1)(a) of the HRA 1998, to take into account the case law of the ECtHR, in which the principle of human dignity also play a pivotal role. Thirdly, also the HTA Code of Practice A on Consent regards dignity as one of the guiding principles for the use of human tissue.[747]

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[742] Code of Practice A, para. 13.
[743] Youngs, 2016, p. 564.
[744] Brownsword, 2001, p. 187.
[745] Youngs, 2016, p. 564 with further reference.
[746] See fn. 736 above.
[747] See 14.3.3.

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Chapter 18

Examples from the contractual practice

CHAPTER 18 Examples from the contractual practice

18.1 Preliminary remarks

The aim of this chapter is to provide a few practical examples of contracts for the use of human tissue. For this purpose, this chapter firstly provides a general overview of the structure of MTAs and it identifies the general characteristics and the most common clauses included in this type of contracts.[748] Secondly, this chapter analyses whether or not and, to what extent, the (relevant) clauses of the various MTAs abide with the law sources applicable to contracts on human tissue identified in this book. Attending to the nature of the contractual parties two types of MTAs were collected and analysed. The first type of contracts is concluded either between or within universities or similar institutions (e.g. research centres). The scope of this type of contracts is generally to conduct non-profit academic research. In the second type of contracts at least one of the parties is a company. In this latter case, the scope of the contract may vary and include research with commercial purposes. Thirdly, in order to provide the reader with an example of the multiple types of contracts (typical and atypical) that can be concluded for the use of human tissue, this chapter studies a type of agreement that does not conform to the typical structure of an MTA: the SGC Open Science Trust Agreement (hereafter: SGC OSTA).

Section 18.2 analyses the first type of MTA. Section 18.3 analyses the second type of MTA. Section 18.4 examines the SGC OSTA and section 18.5 concludes.

18.2 Material transfer agreements between or within academic institutions

For the analysis of this type of contracts, the following model contracts have been chosen:

1) The Brunswick human tissue Material Transfer Agreement (hereafter: Brunswick MTA). This MTA is particularly relevant because, according to the Brunswick website, institutions that have signed for the use of this agreement include some of the most prestigious English universities.[749] For this reason, the Brunswick MTA provides significant insights on the contractual practice regarding the transfer of human tissue in England.

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[748] On the definition and kinds of material transfer agreements see Chapter 1.3 on terminology.

[749] This model agreement is publicly available at <https://arma.ac.uk/updated-brunswick-agreements <accessed 22 October 2018>. Institutions that have sign up for the use of these models are, among others: Arden Tissue Bank. Bangor, Birmingham, Bristol, Cambridge, Cardiff, Durham, Edinburgh, Glasgow, Imperial College London, Kings College London, Leeds, Liverpool, Newcastle, Nottingham, Nottingham University Hospital NHS Trust, Oxford, Portsmouth, Queen Mary & Westfield College, Royal Holloway College, Royal Veterinary College (London), Sheffield, Southampton, Sunderland, Sussex, University College Dublin, University Hospitals Coventry and Warwickshire, University of the West of England (Bristol).

2) The Bristol University Material Transfer Agreement (hereafter: UB MTA).[750]
3) The supply agreement for the provision of human tissue samples and tissue donor information within University College London for research purposes only (hereafter: UCL MTA).[751] In this type of MTA, the transfer of human tissue occurs within the University, i.e. the UCL.

The drafting of these models differs from one another but some common features can be identified. I will address first the clauses that are common to all and then analyse the ones included only in two or one of the three model contracts.

Contractual clauses common to all model contracts:

1) All three models specify that the materials are supplied without cost or free of charge, but the recipient of the material shall reimburse the provider for any reasonable costs that may be incurred when preparing and sending the materials to the recipient.[752] Arguably, clauses prescribing the gratuity of the transfer answer to the rationale that the purpose of MTA between academic institutions is encouraging research and training. In fact, the Brunswick MTA includes a clause that explicitly indicates that "the material is provided in pursuit of the charitable objectives of the parties; that is the advancement of education through research and training".[753] Financial gain is not one of the primary objectives of the parties in this type of MTA.

2) All three models include provisions limiting the use of the transferred material: the material can be used solely for the purpose of the research described in one of the appendixes to the contract.[754]

3) All the contractual models include a clause that prescribes that the use of the materials or the activities of the research project should be carried on in accordance to all applicable laws, including data protection law and the HTAct 2004. In particular, it is of interest that these model contracts prescribe that the codes of practices of the Human Tissue Authority and/or other ethical guidelines and research governance instruments shall be applicable to the contract.[755] These model contracts constitute a perfect example of incorporation into the

[750] Available at: http://www.bristol.ac.uk/media-library/sites/alspac/documents/researchers/data-access/ALSPAC%20non%20HTA%20Material%20Transfer%20Agreement.pdf <accessed 22 October 2018>.
[751] Available at https://www.ucl.ac.uk/ion/sites/ion/files/uclmta_jan_2018_p.docx <accessed 24 October 2018>.
[752] Clause 4 Brunswick MTA, Clause 12 UB MTA; Clause 5 UCL MTA.
[753] Clause 9 Brunswick MTA
[754] Clause 1 Brunswick MTA, Clause 5 UB MTA; Clause B UCL MTA.
[755] Clause 3 Brunswick MTA, Clause 3 UB MTA; Clause 12 UCL MTA.

contract of legal instruments that otherwise would not be legally binding to the parties.

4) It is common to all models to include a clause that prescribes that in the case the original transferor of the tissue revokes or rescinds her consent, the provider institution will require the recipient institution to destroy or return the tissue.[756] The inclusion of this clause is in line with the requirements of the HTAct 2004 the GDPR and the HTA Codes of Practice A and E, which allow the first transferor of tissue or data subject to revoke or rescind her consent at any time.[757] From the fact that the original transferor of the sample could only revoke her consent when the tissue sample has not been anonymized, it can be deduced that GDPR applies to these contractual models: the GDPR applies to data of identified or identifiable persons and not to anonymous or anonymized data.[758]

5) A common clause regarding the identification of the original transferor of the tissue prescribes that the recipient shall not make any attempts to identify the original donor of the sample, and the provider shall not supply the recipient any information that may lead to the identification of the original transferor.[759] In my opinion, the inclusion of this type of clauses might have the intention to protect the validity of the contract in cases when the consent of the first transferor has not been obtained for further use of the tissue and associated data. In fact, section 1(4)(9) of the HTAct 2004 makes an exception to the requirement of consent for the purpose of the research in connection with disorders or the functioning of the human body provided that the research is ethically approved and the person carrying the research is not likely to come in possession of information from which the person from whose the material has been obtained can be identified. In this way, even if the consent of original donor has not been obtained for the use of his tissue in the type of research carried on by the recipient, the contract will still be valid.

Contractual clauses common to at least two models:

1) In relation to consent, the Brunswick MTA and the UCL MTA warrant that, when applicable, consent has been obtained as required by the HTAct 2004 and the HTA Codes of Practice.[760] On the contrary, the UB MTA does not make any representation that the use of the material is free from infringement of third party rights.[761] This latter type of clause might be contrary to the provisions of the HTAct 2004 that require consent for the use of tissue and other relevant materials.

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[756] Clause 13 Brunswick MTA, Clause 7 UB MTA; Clause 2 UCL MTA.
[757] See subsection 14.3.3.
[758] See section 3.4.
[759] Clause 10 Brunswick MTA, Clause 10 and 11 UB MTA; Clause 6 UCL MTA.
[760] Clause 10 Brunswick MTA; Clauses 1and 2 UCL MTA.
[761] Clause 13 UB MTA.

2) Common to the Brunswick MTA and the UB MTA is that the provider institution does not give any warranty related to the quality, safety or fitness for a particular purpose whilst limiting its liability to the maximum permitted by law.[762]

3) The Brunswick MTA and the UB MTA contract models include a prohibition to use the material for administration to human subjects, experiments involving humans, human application or for clinical and diagnostic purposes.[763]

4) The Brunswick MTA and the UCL MTA refer to the definition of material as specified in the HTAct 2004 or by reference to the Appendixes to the contract.[764]

5) Since it is in the interest of academic institutions to establish clear rules pertaining to the ownership of the research results and the publication rights, it is generally accepted that the recipient institution has the right to publish the findings of the research. However, this rule is generally conditioned to the right of the provider to delay the publication of the results. This condition enables the provider to make sure that confidential information is not revealed, that a patent application is not possible with the information of the research results and that the provider of the materials is properly acknowledged in the publication.[765]

6) Common to the Brunswick MTA and the UCL MTA is the inclusion of a clause that requires the consent of the provider institution to keep carrying research in cases where there is a material change in the research of the recipient institution. Arguably, the purpose of this type of clause is to keep the research within the limits of the consent of the original transferor.[766]

7) The applicable law and jurisdiction in these MTAs is, as a general rule, the English one.[767]

Contractual clause included in only one of the models:

1) The Brunswick MTA includes a special provision regarding the obligation of the recipient institution to not compromise or otherwise infringe the confidentiality of information on the donors and their right to privacy.[768] This is the only identified clause that directly makes reference to a human right enshrined in the HRA 1998.

2) The UCL MTA is perhaps the most complete MTA regarding the protection of the original donor of the sample. Firstly, this MTA indicates that the tissue and

[762] Clause 5 Brunswick MTA; Clauses 13 UB MTA.
[763] Clause 2 Brunswick MTA, Clause 6 UB MTA.
[764] Clause A Brunswick MTA, Clause D UB MTA.
[765] Clause 9 Brunswick MTA, Clause 8 UB MTA.
[766] Clause 8 Brunswick MTA, Clause 10 UB MTA.
[767] Clause 14 Brunswick MTA; Clause 15 UB MTA.
[768] Clause 11 Brunswick MTA.

donor information supplied to the recipient have been obtained from living donors from whom written consent was given by the donor.[769] Although written consent is not a requirement included in the HTAct 2004 it is required by the GDPR. Secondly, in this MTA the provider warrants the recipient institution that no payments were made or other inducements given to any donor or next of kin or other consenting person to procure the tissue or donor information.[770] Thirdly, the UCL MTA indicates that the research project may include RNA analysis and gene expression studies in line with the donor consent and with the Codes of Practice of the Human Tissue Authority.[771] Finally, this MTA indicates specifically that tissue will be anonymised by coding (e.g. pseudonomysed).[772] These four provisions are in line with the protection to the donor afforded by the HTAct 2004 and the Codes of Practice of the HTA. It would be desirable that other MTA would include such provisions for the protection of the original donor.

18.3 Material transfer agreements in which one of the parties is a company

This section analyses the Lambert sample materials transfer agreement (hereafter Lambert MTA).[773] The Lambert MTA is a model agreement developed by the Lambert working group and it is intended to be used when a company has allowed a university to use certain materials in connection with a research project.[774] This agreement is intended, among other purposes, to regulate and determine the intellectual property rights of the parties. Since IP rights are not at the core of this book's research, this section will focus on the contractual provisions related to the limits to validity of contracts explored in this book and therefore, it will exclude the analysis of the provisions regulating IP rights.

The Lambert MTA provides a list of definitions that are not included in the MTA analysed in the previous section. It defines, among others the following terms: academic publication, intellectual property, know-how, an improvement, the materials, the price, the principal investigator, the project, the results, the term and the territory.

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[769] Clause 2 UCL MTA.
[770] Clause 4 UCL MTA.
[771] Clause 4 UCL MTA
[772] Clause 4 UCL MTA
[773] Available at: https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit#model-agreements-between-the-pharmaceutical-and-biomedical-industries-universities-and-the-nhs. Last accessed 5 November 2018.
[774] According to their website "the Lambert agreements and supporting materials are to be treated as crown copyright. They are free for universities, institutions and companies to use, adapt and re-use for the purpose of undertaking collaborative research. Where practicable, the source of the Lambert Agreements and supporting materials should be cited. See: https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit#model-agreements-between-the-pharmaceutical-and-biomedical-industries-universities-and-the-nhs

In this MTA the Company will provide the Materials to the University only for the project and not for any commercial purpose or commercially sponsored research without first obtaining the company's written consent.[775]

Similarly to some of the provisions of the MTA of analysed in the previous section, according to the Lambert MTA, the university will use the materials in accordance with all applicable laws, regulation, and government guidelines.[776] Once again, a contract is giving governance regulations a binding effect for the parties.

The Lambert MTA, unlike the MTAs between academic institutions, allows for the possibility of payment in exchange of the transfer of the materials.[777] This is perhaps the most striking difference in relation to the contracts analysed in the previous section. In the Lambert MTA, obtaining economic profit is not excluded from the agreement. Furthermore, it is striking that no reference whatsoever is made to the original donor of the material and her consent. It would be desirable that also MTA with commercial purposes include clauses for the protection of the original source of the materials.

18.4 SGC OSTA

The SGC is a charity registered in the UK for the purpose of increasing research in new areas of human biology and drug discovery.[778] The consortium includes the Universities of Oxford, Toronto, the Karolinska Institute, Unicamp and Goethe Universiteit.

Unlike MTAs in which a bilateral agreement is concluded between provider and recipient, the Structural Genomics Consortium Open Science Trust Agreement (SGC OSTA) is an agreement in which the recipient of the materials agrees to become a trustee of the research material.[779]

According to the SGC's website: "a trust such as the OSTA is a legal mechanism under which an appointed trustee takes legal possession of property but assumes a duty to use or manage that property to benefit certain beneficiaries, which can be third parties and/or the public. With the OSTA, unlike under an MTA, by becoming a trustee of SGC-provided research material, a recipient is undertaking a specific duty to benefit the public through open science."[780]

Some of the obligations of the trustee include:

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[775] Clause 2.2 Lambert MTA.
[776] Clause 2.4 Lambert MTA.
[777] Clause 3 Lambert MTA.
[778] For information on the Structural Genomics Consortium see: https://www.thesgc.org/click-trust/faqs. Last accessed 5 November 2018.
[779] Agreement available at: https://www.thesgc.org/click-trust. Last accessed 5 November 2018.
[780] Ibid.

1) Not seeking or enforcing intellectual property rights covering the material, which could deter or prevent others in the research community from using the material to further the public good.

2) To place the research findings and data resulting from their work with the material into the public domain, which helps to accelerate discovery.

Furthermore, the trustee is permitted to disseminate "(…) the material to other researchers who likewise agree to become trustees, thus expanding the community of researchers committed to open science for the public good."[781]

In clear contrast with the Lambert MTA, the intention behind the SGC OSTA is to promote open science among researchers and to treat human tissue and other materials as public goods to be shared broadly. However, like in the Lambert MTA no reference is made in the OSTA to the original donor of the tissue.

18.5 Concluding remarks

The model contracts analysed in this chapter are useful to provide a broad overview of the clauses included in contracts for the transfer and use of human tissue.

Three main conclusions can be derived from this analysis. Firstly, a bigger protection to the original transferor of the tissue is afforded in contracts that do not have as their main scope commercial research. On the one hand, MTA's between academic institutions and the OSTA tend to treat human tissue as a good that cannot be object of property or commercial dealings. On the other hand, the Lambert MTA allows for a payment (above the normal compensation for the transportation and transfer costs) in exchange for the transfer of human tissue. Secondly, it would be desirable to include in all types of contracts clauses that protect the identity of the original transferor and that warrant that consent has been obtained according to all applicable laws. Finally, it is particularly interesting how all MTA's give a binding effect to ethical guidelines and regulations that otherwise would not be directly applicable to the contract. This contractual practice demonstrates the growing importance of ethical guidelines and other soft regulatory documents in the field of biolaw, in general, and for the transfer of human tissue, in particular.

[781] Ibid.

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Chapter 19

Concluding remarks on contracts on human tissue under the law of England and Wales

CHAPTER 19 Concluding remarks on contracts on human tissue under the law of England and Wales

In England & Wales, the framework for the determination of the validity of contracts on human tissue can be distilled from the interaction of several law and governance sources. The main statutory instrument on the removal, use and storage of human tissue is the Human Tissue Act 2004, which was enacted following the retention of organs scandals of the Bristol Royal Infirmary and the Alder Hey Children's hospital in Liverpool.[782] The HTAct (s1 (1)-(3)) regulates the activities that can be lawfully performed with appropriate consent, including the storage and use of relevant material that comes from bodies of living persons.[783] Schedule 1 of the HTAct lists the purposes for which it is necessary to obtain consent when carrying an activity described in s1 (1)-(3). The following scheduled purposes are relevant for the subject matter of this book, in particular, because they could be achieved via the conclusion of a contract on human tissue: obtaining scientific or medical information about a living person which may be relevant to another person; public display; research in connection with disorders or the functioning of the human body and, transplantation. The HTAct (s1 (4)-(9)), however, excepts from the requirement of consent, the use and storage of relevant material from a living person for the purposes of research in connection with disorders or the functioning of the human body, provided that the research is ethically approved and it is to be carried in a way that the person conducting the research is not in possession, or likely to come in possession of information from which the person from whose the material has come can be identified. This exception is in line with the provisions of the General Data Protection Regulation that allow the processing of data without the consent of the person for achieving scientific purposes when the necessary safeguards regarding for the personal information of the subject have been put into place.[784]

Although the whole normative body of the HTAct (with certain exceptions) is built around the idea of consent, the HTAct does not define this notion. It is the HTA Code of Practice A on Consent that indicates that appropriate consent must come from the person entitled to consent and indicates that its form of expression is irrelevant for its validity unless the HTAct requires otherwise.[785] Therefore, the form of expression of consent for the conclusion of contract on human tissue does not require any specific form, although it would be preferable to obtain it in writing.[786] Moreover, according to Code of Practice A, it is possible for the person to attach conditions on consent to restrict the type of activities

[782] On these scandals see section 14.2above.
[783] See subsection 14.3.2 above.
[784] See fn. 138 above
[785] See fn. 586 above.
[786] See fn. 591 above.

allowed to be performed with the tissue.[787] Such conditions would place limits not only to the contract between the first transferor and the first recipient, but also, to the possible future contracts between the first and further recipients of the tissue.

The HTAct prescribes two types of restrictions of activities on human tissue that arguably should also apply to contracts on human tissue.[788] The first type of restriction (section 8(1) HTAct) indicates that a person commits an offence if she uses or stores material for a purpose different than a qualifying purpose. The second type of restriction refers to the general prohibition of commercial dealings in human material for transplantation(s 32(1)). Accordingly, a contract concluded for the purpose of dealing commercially with human tissue for transplantation should be considered invalid.

Since the HTAct does not regulate consent for the purposes of removal of human tissue, the legal regime for this purpose can be found in the common law rules, the Mental Capacity Act and the Department of Health guide to consent.[789] Particularly relevant are the requirements of capacity, voluntariness and appropriate information. Arguably, if one of these requirements is missing, the contract should be declared invalid.

Regarding the common law doctrines on the illegality of contracts, this book identified seven of the headings of illegality and public policy proposed by *Treitel* and/or *Anson*'s that could constitute limitation to the validity of contracts on human tissue: contracts amounting to a legal wrong, contracts to commit a crime, contracts to commit a civil wrong or perpetrate a fraud, agreements which are in themselves lawful but are used for an unlawful purpose, agreements in which the method of performance is unlawful, contracts restricting personal liberty, and contracts contrary to good morals.[790] Although the examples brought forward in this book in relation to the different headings of illegality and public policy are only examples of the possible interplay between the different source of law and governance in matter regarding human tissue, they do illustrate how these headings could possibly constitute the grounds for the determination of the limits to the validity of contracts on human tissue stemming from statutory sources (e.g. HTAct), from other common law sources (e.g. the legal regime on consent from the living), as well as the grounds for the assessment of such validity when the purposes are not explicitly or implicitly regulated by law or when the contract has a highly disputed moral content.

Regarding the effect of fundamental rights on the validity of contracts on human tissue, it seems that human dignity and other fundamental rights could have a

[787] See fn. 594 above.
[788] See subsection 14.3.4 above.
[789] See fn. 608 above.
[790] See section 16.4. above.

role in the determination of such limits. From the position of courts and scholars alike it can be derived that the HRA has at least an indirect effect (in one of its multiple variations) on disputes between private parties,[791] including disputes arising from contracts on human tissue. Similarly, from the harmonic reading of the HRA 1998 and the HTA Codes of Practice A and E, it seems possible that the principle of human dignity can constitute the grounds for the identification of limits to these of type of contracts.

Finally, from the analysis of the model contracts it can be derived that, although some clauses might clash with the legislation regulating the rights of the original transferors of the tissue, these contracts comply with the limits identified and described in this book. However, it would be desirable that the inclusion of clauses for the protection of the rights of the original donor of the tissue becomes a generalized contractual practice in the drafting of contracts, with or without, commercial purposes.

[791] See section 17.4. above.

Part 5

COMPARATIVE ANALYSIS

20

Chapter 20

Comparative analysis

PART 5 COMPARATIVE ANALYSIS

CHAPTER 20 Comparative analysis

20.1 Introduction

This Chapter is devoted to the comparative analysis of the possible limits to the validity of contracts on human tissue in the legal regimes of England and Italy, as complemented by the supranational law sources of the European Union.[792] So far, this book has singled out and analysed the supranational and European law sources, the Italian and the English legal regime in three different individual parts, corresponding to Parts 2, 3 and 4 of this work. In order to facilitate the comparative analysis of the different contracts on human tissue, this Chapter will not mirror such structure, but instead will be divided in five sections. Section 20.2 deals with the comparative analysis of the types of contracts on human tissue that have been explicitly prohibited or allowed by law. As it has become evident in previous chapters, various limits to the validity of contracts on human tissue arising from the analysis of the different law sources are equally applicable to more than one of the three types of contracts considered by this work, i.e. gratuitous and non-gratuitous contracts between the first transferor and first recipient and contracts between the first and subsequent recipients. For this reason, Section 20.3 compares the limits to the validity of contracts on human tissue in the legal systems of Italy and England that are not specific to a particular type of contract by reason of their non-gratuity or by reason of the condition of the contractual parties.

However, because the elements of non-gratuity of the contract, and the position of the contractual parties give rise to specific limits that demand an independent analysis, Sections 20.4 and 20.5 will compare the limits to the validity of non-gratuitous contracts and contracts between the first and subsequent recipients respectively, insofar as they have distinctive traits and limits that deserve an independent treatment. The internal structure of these sections corresponds to the main points of convergence and divergence of the legal systems analysed (e.g. data protection, consent, human dignity).

20.2 Contracts on human tissue explicitly prohibited or allowed by law

Both in Italy and England there are certain types of contracts on human tissue explicitly prohibited by law when the intention is to use the tissue for transplantation. In Italy, the transfer of tissues and cells for grasp or transplant is prohibited if performed for remuneration or for the purposes of

[792] On the method used for the comparative analysis see section 1.4 on Methodology.

commercialization.[793] In this book I differentiate the concept of remuneration from the one of compensation. Compensation refers to a certain amount of money given to the donor to compensate expenses related to the act of disposition, e.g. transport or accommodation. Remuneration refers to a payment that goes above the compensation for expenses.

In England, the list of activities explicitly prohibited by law is more detailed than in Italy and includes the following commercial dealings of any material that consists or includes human cells (henceforth: material) if intended for transplantation: 1) giving or receiving a reward for the supply of, or the offer to supply any material; 2) seeking to find a person willing to supply any such material for reward; 3) offering to supply any material for reward; 4) initiating or negotiating any arrangements involving the giving of a reward for the supply of, or for an offer to supply, any material; 5) taking part in the management or control of a body of persons corporate or incorporate whose activities consist of or include the initiation or negotiation of such arrangements.[794] A contract that includes any of the aforementioned activities should therefore also be considered as prohibited by law.[795]

However, under English law there are two notorious exceptions to the prohibition of commercial dealings on human tissue. According to the first exception –typical of the common law tradition– if human skill is applied to the material (e.g. fixing it in paraffin blocks) it then becomes an object of property and can therefore be also the object of commercial dealings. [796] According to the second exception, cell lines, as any other material created outside the body, are excluded of the prohibition of commercial dealings.[797]

Although in both legal systems there is a prohibition of commercial dealings on human tissue, the ban is wider in scope in Italy, since it does not allow for any of the aforementioned exceptions. Furthermore, since the application of human skill on human tissue under English law would enable a person to escape the scope of application of the prohibition of commercial dealings, one could argue that such prohibition only applies, *prima facie*, to contracts between the first transferor and the firs recipient.

[793] Article 2, 4, and 22 law n. 219/2005 (blood and hemoderivatives); Article 12 legislative decree n. 191/2007 (tissues and cells).
[794] Section 32 HTAct.
[795] On the relation between illegality and this prohibition see below 20.4
[796] Ibid. For case law on the human skill exception see fn. 604 above.
[797] Section 54(7) HTAct.

20.3 General limits to the validity of contracts on human tissue

20.3.1 Stemming from supranational fundamental rights sources

There are significant differences and some practical similarities between the Italian and English legal systems regarding the incorporation and effect of supranational fundamental rights law (UDHR, ECHR, Oviedo Convention and CFREU) and therefore, there are also differences in the possible fundamental rights related limits to the validity of contracts on human tissue.

Although both legal systems are dualistic in what concerns the incorporation of international law, in Italy, the UDHR has the status of consuetudinary law and in England it does not form part of its domestic law. The ECHR has been incorporated in both national legal systems and in both it has a special status: in Italy, domestic law cannot modify the rights enshrined in the law n. 848 of 1955,[798] which incorporates the ECHR, and in England, the HRA 1998, which incorporates the Convention, cannot be object of the doctrine of implied repeal.[799]

Regarding the Oviedo Convention, although it was only incorporated in the Italian legal system, its practical effects are very similar in both England and Italy. The reason for this similarity is that although Italy incorporated it with the law n. 145 of 2001, the government has not issued the necessary legislative decrees to adapt it, which results in a *de facto* inapplicability. However, in both legal systems, the Oviedo convention has, at least, an interpretive value.[800]

Regarding the CFREU in Italy, scholars have argued that it holds an interpretative value, while England opted out from its application with Protocol 30 to the TEU.

Taking into account the aforementioned considerations, in Italy the relevant norms of the UDHR, ECHR, Oviedo Convention and CFREU may constitute limits to the validity of contracts on human tissue. In the English legal system, arguably only the provisions of the HRA 1998 and the Oviedo Convention have an effect for the interpretation and determination of the limits to the validity of contracts on human tissue (see Chapter 2).

20.3.2 Stemming from EU supranational sources: data protection law

Because of the complete direct effect of EU Regulations, the GDPR imposes direct and indirect limits to the validity of contracts on human tissue both in England

[798] See fn. 110 above.
[799] See fn. 52 above.
[800] See section 2.6.

and Italy.[801] In particular, contracts that involve the processing of personal data are bound to the principles of the GDPR. These principles include: fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation and, integrity and confidentiality. Furthermore, these limits apply to pseudonymised data but not to anonymous information. In other words, any contract on human tissue that involves the processing of pseudonymized or identified data is bound by the principles of the GDPR. The direct limits relate to the *consent* of the person for the processing of data. The indirect limits include the creation of certain pre-contractual *information* duties regarding the contracts on human tissue that involve the processing of data. Both types of limits apply for all types of contracts that encompass any of the activities that fall within the scope of the aforementioned regulation.

More specifically, the provisions of the GDPR limit –in different ways and on various grounds– the conclusion of contracts on human tissue that involve the processing of genetic or health data. Regarding the direct limits, a first limit can be deduced from the Article 9.2 GDPR, which only permits the processing of these types of data if explicit consent of the data subject is given for one or more purposes. From this provision, it necessarily follows that consent of the data subject (first transferor of the tissue) is required for any contract involving the processing of health and genetic data. The requirement of consent applies without distinction for both gratuitous and non-gratuitous contracts. Other direct limits can be deduced from Article 7 GDPR, which prescribes the conditions for consent for the processing of data. According to this provision, when consent is given in the context of a written declaration that also involves other matters than the processing of data, the request for the consent of the data subject (first transferor of the tissue) should be presented in such a way that it is clearly distinguishable from the other matters. If for example, a contract for the transfer of human tissue and the processing of the genetic data therein contained, also involves the removal of the tissue from the person's body, it should be made clear to the data subject that the consent for the removal of the tissue is different from the consent for the processing of the data. Another limitation to contracts on human tissue stemming from Article 7 GDPR is the right of the data subject (first transferor) to withdraw her consent at any time. Contractual clauses limiting this right of withdrawal cannot be included in contracts for the transfer of human tissue that entail the processing of health and genetic data.

Regarding the indirect limits, Article 13 GDPR requires the data controller (first recipient of the tissue) to provide the data subject with the following information: the purposes of processing for which the personal data are intended as well as the legal basis for the processing; the period for which the

[801] On the GDPR see section 3.4.

personal data will be stored, or if that is just not possible, the criteria used to determine that period; and the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal. Depending on the legal system, the obligation to provide this information could constitute the grounds for pre-contractual duties or even for the mandatory inclusion of contractual clauses as in the case of the criteria used to determine the storage period of the data.

In what concerns the matters covered by the GDPR, the scope of protection and the limits to the validity of contract on human tissue are identical for both the legal systems of Italy and England.

20.3.3 Stemming from the rules and doctrine on the invalidity of the contract

The limits to the validity of contracts on human tissue between the first transferor and the first recipient stemming from the rules and doctrine of the invalidity of the contract vary significantly from Italy to England.

The Italian legal system knows three different forms of invalidity of the contract: nullity, annullability and rescindability.[802] From these, rescindability is arguably the category that finds less application to contracts on human tissue. However, annullability and nullity constitute, to a big extent, the grounds for the identification of the limits to the validity of contracts on human tissue in the supranational and national legislation. In the case of annullability, it will be the concrete analysis of the contract that will determine its validity. In particular, the category of mistake might prove useful for the analysis of cases where the original transferor of the tissue made a mistake on the nature of the contract she was concluding, for example when the person believed she was concluding a contract for non-profit research on a particular disease and the contractual purpose was in reality the commercial exploitation of this research. The category of fraud might be relevant for the analysis of cases where the person was deceived to conclude a contract, for example when the person was made to believe to transfer human tissue for purely diagnostic purposes while in reality the material was to be used for obtaining a patent which would secure considerable financial gain for the patent holder.

The nullity of the contract is particularly useful to determine the limits to validity of contracts on human tissue because of the illegality of the cause or object of the contract on the grounds of their contrariety to mandatory norms, public order and good morals. Under Italian law, these categories find application not only within the realm of private law, but also refer to constitutional principles (in the cases of mandatory norms and public order) and constitutional and fundamental

[802] See Chapter 5.

rights (in the case of good morals).[803] In fact, Italian scholars and courts admit the application of fundamental rights through the interpretation of open norms of private law. This idea seems to be confirmed by the fact that, although in matters not directly related to the validity of contracts on human tissue, Italian courts have given direct application to some constitutional articles, among which, Article 2 in relation to the good faith clause; Article 3 in relation to the general principle of equality and general contract law; and Article 32, particularly in relation to labour contracts.[804]

For this reason, the general constitutional framework for the regulation of the acts of disposition of the human body constitutes another normative corpus in which the limits to the validity of contracts on human tissue can be found. This normative constitutional framework includes Article 2, 13, and 32 Cost.[805]

In England, the validity of the contract can be challenged based on the common law doctrines of illegality and public policy. Unlike the Italian legal system, where the scholarly category of invalidity has its legal grounds in the civil code (and other statutes), in England, the doctrines of illegality and public policy have been essentially developed by the courts, and further categorized by legal literature. For this reason, there are no unanimous definitions of illegality and public policy, and legal scholars have created their own different taxonomies to explain these categories. This work has identified seven headings of illegality and public policy, stemming from scholarly literature on the matter, that could possibly constitute limits to the validity of contracts on human tissue: contracts amounting to a legal wrong, contracts to commit a crime, contracts to commit a civil wrong or perpetrate fraud, agreements which are in themselves lawful but are used for an unlawful purpose, agreements in which the method of performance is unlawful, contracts restricting personal liberty, and contracts contrary to good morals.[806] These headings are relevant for the determination of the limits to the validity of contracts on human tissue, in general, for at least three reasons:

1) For the determination of the limits to the validity of these contracts stemming from statutory sources (e.g. HTAct and GDPR). In particular, the headings 'contracts amounting to a legal wrong' and 'contracts to commit a crime', are useful for this purpose. In fact, a contract is illegal if its conclusion amounts to a legal wrong (for example if it is implicitly or explicitly prohibited by statute), or if its purpose is to commit a crime. Both the HTAct and GDPR include explicit and implicit prohibitions that would preclude the conclusion of certain types of contracts on human

[803] See section 7.4 above.
[804] See fn. 327.
[805] On this general constitutional framework see section 6.4 above
[806] See section 16.4.

tissue, and the HTAct, in particular, considers as offences a range of activities described, for example, in articles 8 and 32.

2) For the analysis of the (in)validity of contracts on human tissue stemming from the legal regime of consent under common law, as in the cases of the heading 'contracts to commit a civil wrong' or 'contracts to perpetrate fraud': if, for example, the first and a subsequent recipients of human tissue are concluding a contract in order to circumvent the requirement of consent of the first transferor (when needed), one could speak of a contract amounting to the commission of a civil wrong.
3) For the determination of the validity of a contract on human tissue when its purpose has not been explicitly or implicitly regulated by law (e.g. the use of human tissue for an artwork).

There are points of contact and points of divergence between the limits to the validity of contracts on human tissue arising from the grounds of invalidity of contracts in Italy and England. Although the terminology used in both legal systems is different, perhaps the strongest convergence arises from the fact that in both legal systems a contract is illegal if its purpose (in England) or object (in Italy) is prohibited by statute (in England) or mandatory law (in Italy). In fact, it is from this common characteristic that one could derive the illegality of contracts stemming from the applicability of provisions of the GDPR and other statutes.

Moreover, in both legal systems the category of good morals could play a role in the determination on the validity of contracts on human tissue, with the proviso that in England the concept of good morals does not include fundamental rights, as it is the case in Italy.[807] Although only in the Italian legal system it is possible to directly apply constitutional principles and fundamental rights via the general clauses of private law of public order and good morals for the determination of the validity of contracts on human tissue, in England it is possible to interpret the content of the contract in the light of the rights enshrined in the ECHR, and according to some scholars, even declare the unenforceability of certain contractual clauses.[808]

Finally, because of the relatively open character of the notions of public order and public policy in both legal systems, one could argue that –in the determination of the validity of contracts on human tissue– both English and Italian judges have a broad range of manoeuvre and flexibility to navigate between different legal categories available and determine the most appropriate legal solution on a case by case basis.

[807] See subsection 5.2.3.
[808] See fn. 745 above.

20.3.4 Stemming from the protection of human dignity and other fundamental rights

The limits to the validity of contracts on human tissue arising from the protection of human dignity and other fundamental rights in both the Italian and English systems are abstract limits that may find a concrete manifestation in their application by the judge on a case by case basis.

To the date, there is no case law on the relation between the protection of fundamental rights and the validity of contracts on human tissue in any of the aforementioned legal systems. However, from the general functioning and scope of the system of protection of fundamental rights in each of these countries, it is possible to imagine – *in abstracto* – how, and to what extent, fundamental rights can have a bearing in the determination of the limits to the validity of contracts on human tissue.

There are well known differences between the legal systems of Italy and England regarding the scope and protection of fundamental rights. Perhaps the most prominent formal difference is the presence of a written constitution in the Italian legal system. The Italian constitution includes a number of citizens' rights and duties (Articles 13 to 54 Cost.) but perhaps the most important constitutional legal basis for the recognition of fundamental rights is Article 2 Cost.

Article 2 Cost., according to a widespread view among Italian scholars, is a general constitutional clause that allows, not only for the recognition of new emerging values, but also to consider some rights that have not been included in the constitution as inviolable, e.g. right to honour, right to respect private life.

This feature of Article 2 Cost. is particularly relevant for the determination of the possible limits to the validity of contracts on human tissue because it allows for a certain degree of flexibility in the recognition of new emerging values, which in turn would allow the Italian legal system to keep the pace with the rapid technological innovations and new ethical challenges arising from the developments of biotechnologies involving human tissue.

Furthermore, although human dignity is only mentioned once in the entire Italian Constitution, Article 2 Cost. implicitly acknowledges the fundamental principle of human dignity and the inviolability of the human person.

Since Italian scholars and courts admit the direct and indirect (through the interpretation of open norms of private law) horizontal effect of fundamental rights on private relationships, the recognition of human dignity as a (supra)constitutional principle and fundamental right under Italian law has practical implications for the determination of the limits to the validity of

contracts on human tissue: a contract on human tissue that is contrary to human dignity could be considered invalid on the grounds of its contrariety to public order and good morals.

In the absence of a written constitution, the system of protection of fundamental rights in England stems from the incorporation of the ECHR via the HRA 1998. Although there is still an ongoing debate around the horizontal effect of the fundamental rights enshrined in the HRA 1998, it would appear from case law and literature on the matter that the developments in the field tend towards the indirect horizontal effect in one of its weaker variations.[809] In this sense, fundamental rights could be used to create new interpretations of doctrines and private law rules. Some scholars have even maintained that contractual provisions should be interpreted in a manner that is consistent with the Convention rights, and when that operation is not possible, contractual clauses could be considered unenforceable on the grounds of their contrariety to public policy.[810]

Similarly to what occurs in Italy, the principle of human dignity cannot be found in the wording of the ECHR or the HRA 1998. However, because human dignity constitutes the implicit foundation of the HRA 1998, and because the obligations of English courts to take into account the case law of the ECtHR, the principle of human dignity may play a role in the determination of the limits to the validity of contracts on human tissue.[811] In addition to the principle of human dignity, the right to respect for private life (in relation to personal data) enshrined in the HTA 1998 may constitute a limit to the validity of contracts on human tissue.

In England, the respect to the principle of dignity in relation to the use of human tissue can, additionally, be derived from the wording of the HTA Code of Practice A on consent.[812] This code prescribes that dignity should be one of the guiding principles that persons involved in the use of human tissue should follow. Such principle entails, according to same code, the protection of the privacy of the person.[813]

Finally, also the supranational sources regarding the protection of fundamental rights have different application in Italy and England. In both England and Italy the provisions of the Oviedo Convention have an interpretative value, e.g. the principle of primacy of the human being (Article 2), the right to private life and right to information (Article 10), and the chapters on the human genome (Chapter IV) and scientific research (Chapter V). The relevant provisions of the CFREU (Articles 1, 3, 7, 8, 17) would only indirectly apply to Italy.

[809] See section 17.4 above.
[810] Youngs, 2016, p. 187
[811] See section 17.5 above.
[812] See fn. 583 above.
[813] Ibid.

20.3.5 Stemming from the relation between the protection of physical integrity and health, and consent

The limits to the validity of contracts on human tissue arising from the protection of physical integrity and health on the one hand, and the legal regime on consent on the other, are very different in the Italian and English legal system. These differences arise from the way each of these legal systems affords protection to these rights. While in Italy, the right to health – which includes the protection of physical integrity – is explicitly considered as a fundamental right and collective interest by Article 32 of the Constitution, in England the protection of physical integrity stems from the principles of personal autonomy, self-determination and consent. Furthermore, while in Italy the "permanent reduction of physical integrity" is included in Article 5 C.C. as a direct limit to the validity of the acts of disposition of the human body (which include human tissue), in England the removal of tissue from living persons (which affects physical integrity) is regulated by the rules of common law, the Mental Capacity Act 2005, and the guidelines issued by the Department of Health. The following paragraphs will explore in more detail these differences.

The saying "all roads lead to Rome" could not be truer in the analysis of the limits to the validity of contracts on human tissue stemming from the protection of physical integrity and health in the Italian legal system. In fact, three different roads lead us to the constitutional right to health as a limit to such contracts. The first road is the horizontal application of the fundamental right to health in private relations involving the disposition of human tissue.[814] The second road is the interpretation of the limit of the "permanent reduction of physical integrity" of Article 5 C.C. in the light of the constitutional right to health.[815] The third road is the interpretation of Article 50 of the Penal Code, which prescribes that the one who violates or threatens a right with the consent of the person who can validly dispose of this right, is not punishable. Since Article 50 C.P. does not indicate what should be understood as a disposable right, such legal condition should be filled by the normative content of the constitutional right to health.[816]

The content of constitutional right to health in Italy stems from the coordinated reading of Articles 13 and 32 Cost. These articles allow determining the constitutional core and limits to the right of the individual to dispose of her body.[817] One the one hand, Article 13, according to a broad interpretation currently supported by the Italian Constitutional Court, includes within its scope of protection, not only individual freedom against physical coercion, but also the moral freedom and social dignity of the person when she is subject to moral or

[814] See section 6.4 above.
[815] See section 7.3 above.
[816] See section 8.3 above.
[817] See fn. 349 above.

psychological pressure. According to this line of reasoning, personal freedom projects itself in the personal right to dispose about one's own body, free from coercions directed to hamper or force the legitimate use of such right. On the other hand, Article 32, one of the most significant personalistic manifestations of the Italian constitution, includes the protection of physical integrity and the right to health within its scope of application. However, in the Italian debate, it remains contested whether these rights entail the disposability of the human body. According to some scholars, the unitary notion of health (which includes physical integrity and mental health) embodied in Article 32 Cost., and Article 13 allow to consider severed parts of the human body (including human tissue) as object upon which property rights can be exercised.[818] In support of this argument it has been sustained that the right to health encompasses not only the passive aspect (i.e. the protection of physical integrity from external interferences), but also an active aspect that manifests itself in the freedom of deciding about one's physical being.[819] Some other scholars argue that the general rule stemming from Article 32 is the non-disposability of the human body.[820] It would appear that in the Italian debate, both positions could be convincingly argued from a constitutional perspective. From these considerations it follows that the balancing of conflicting rights –physical integrity and right to health vs. the freedom of deciding about one's body– in cases involving contracts on human tissue should be done on a case by case basis.

In England, in the absence of a fundamental right to health, the limits to the validity of contracts on human tissue arise from the principles of personal autonomy, self-determination and consent. With regards to the latter, it is possible to identify two different sets of rules that may impact the validity of such contracts. The provisions contained in the HTAct and the accompanying codes of practice integrate the first set of rules. These rules apply to the use and storage of human tissue. The second set of rules comprises the common law rules on consent and the guidelines on consent issued Department of Health. These rules apply to the taking of human tissue from the living.

With regards to the first set of rules, the HTAct makes consent the fundamental principle underpinning the lawful storage and use of human tissue.[821] In fact, obtaining consent constitutes a necessary requirement for a variety of purposes of storage and use of human tissue. In particular, consent is necessary for research in connection with disorders, or the functioning of the human body. However, for the latter research purpose, the HTAct also prescribes that consent is not needed for the use and storage of human tissue that comes from a living

[818] See fn. 362 above.
[819] See fn 368 above.
[820] See fn. 363 above.
[821] See subsection 14.3.1 above.

person provided that the research is ethically approved in accordance with the regulation of the Secretary of State and it is to be carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the person from whose tissue has come can be identified. This exception to the requirement of consent, in line with a similar exception included in the recent GDPR, was included because of the fear of many researchers that research would be seriously hampered if consent constituted a requirement in relation to surplus tissue originally obtained for other purposes. Although the HTAct does not include a definition of consent, the HTAct Code of Practice A on Consent specifies that in order to be valid, consent must be given voluntarily by a person with a capacity to agree and understand the activities and risks involved. Finally, according to the same Code of Practice, the form of expression of consent is irrelevant for its validity, unless the HTAct requires it to be in writing. These rules have direct consequences for the determination of the limits to the validity of contracts on human tissue. Firstly, this books argues that, because the HTAct does not permit the use and storage of human tissue without the consent of the first transferor, any kind of contract that involves the use or storage of human tissue without her consent may be considered illegal under the heading 'contracts amounting to a legal wrong'.[822] Secondly, this books maintains that the exception to the requirement of consent included in the HTAct regarding the use and storage of tissue gives rise to further limits to the validity of contracts on human tissue: a contract for the purposes of research in connection with disorders or the functioning of the human body may be considered as amounting to a legal wrong when the research lacks the correspondent ethical approval, or does not guarantee that the researcher does not come in possession of the personal information of the first transferor of tissue. Finally, the question arises of whether or not consent for a contract that involves the use of human tissue and the data associated to it should be expressed in writing. The HTAct does not require it.

With regard to the common law rules on the taking of human tissue from the living it has been argued in the English debate that the legal principle of consent is an expression of the right of the person to decide what happens to her own body. In that sense, granting the individual the right to bodily integrity protects personal autonomy. For this reason, when a breach of consent for the taking of human tissue occurs, the right to bodily integrity is also violated and the actor of the violation may be liable for the torts of battery and, under certain circumstances, for the tort of negligence.[823] Furthermore, both the Codes of Practice A (on consent) and E (on research) accompanying the HTAct refer to the Mental Capacity Act 2005, and the Department of Health to Consent.[824] From the

[822] See section 16.4 above.
[823] See section 15.2.
[824] See section 15.1.

reading of all these statutory provisions and soft law documents it can be derived that for the obtaining of consent, the elements of capacity, voluntariness and appropriate information are necessary. The following should be covered under the category of appropriate information: the risks associated to the procedure, what the samples will be used for, how the results of the research might impact the first transferor's interests, and the intention of future storage and use of the tissue samples. Once again, this book maintains that it is possible to consider a contract on human tissue as illegal is one if the aforementioned elements of consent is missing.

Comparing the limits to the validity of contracts stemming from the relation between the protection of physical integrity and health, and consent, in the legal systems of Italy and England it is possible to observe some substantive similarities and some formal differences. The most striking substantive convergence between the two legal systems is that in both the relationship between the rights to bodily integrity and consent stems from the more abstract principle of personal freedom or personal autonomy. This convergence somehow blurs the more formal distinction between a legal system where personal integrity and health are protected via constitutional rights (Italy) and one where the right to bodily integrity derives from a liberties-based approach (England). This convergence seems to be confirmed by the idea that in both legal systems a contract on human tissue that lacks the consent of the first transferor should be considered, *prima facie*, as illegal. In both legal systems there is a close link between non-contractual liability and the illegality of the contract. In England, this relationship arises from the torts of negligence and battery, and in Italy from Article 50 C.P. in connection with general tort law.

Finally, there is a clear distinction in the way both legal systems afford statutory protection of consent in relation to the use of human tissue. In England, the HTAct, which regulates human tissue, is essentially based on the notion of consent. In Italy, the relation between consent and the use of human tissue only becomes apparent through the interpretation of Article 5 C.C. in the light of constitutional rights and/or Article 50 C.P.

20.4 Limits to the validity of non-gratuitous contracts on human tissue between the first transferor and the first recipient

The previous section compared the limits to the validity of contracts on human tissue that may be applicable to all types of contracts, regardless of whether the contract is concluded gratuitously or non-gratuitously. However, the element of non-gratuity of the contract gives rise to particular questions regarding its validity. For this reason, this section explores the differences and similarities between Italy and England regarding the limits to validity of non-gratuitous contracts in particular.

In the Italian and English legal system, the debates around the possibility of concluding non-gratuitous contracts on human tissue have two different gravitational centres. In Italy, the debate has its contemporary origin in the provisions of the CFREU[825] and Oviedo Convention[826] that prohibit financial gain from the human body and its parts, as such. In England, since both the CFREU and the Oviedo Convention are not directly applicable, the debate focuses, to a large extent, on the inexistence of property rights on human tissue. One could also venture the idea that such differences in the debate arise from the differences in the legal relevance of fundamental rights in both legal systems. That being said, the aforementioned considerations, i.e. the prohibition of financial gain and the inexistence of property rights, are only the general rule in both legal systems, but some additional characteristics of the debate somehow soften such general rules. In Italy, for example, a scholarly position maintains that it is possible to speak of property rights of fruition and unlimited disposition of the detached parts of the human body[827] and in England, some scholars have also considered human dignity as an element to be considered when analysing the validity of contracts on human tissue.[828]

In the Italian debate, several scholarly arguments gave been advanced against the lawfulness of non-gratuitous contracts on human tissue. The first argument derives from the fact that, in Italy, the legal regime of the acts of disposition of the human body (including human tissue) emerges from the interplay of national and supranational legal sources that revolve around the principles of self-determination, gratuity, solidarity and external controls. Since these principles, in turn, fill the content of the notion of public order of the Italian Civil Code and the notion of gratuity is considered part of the public order clause under Article 1418 C.C., then, arguably, a non-gratuitous contract for the transfer of human tissue ought to be considered illegal because of the illegality of its cause or the object. A second argument, closely related to the previous one, maintains that since Article 3 CFREU is included in the Chapter of human dignity, such principle clearly excludes the objectification of the human boy and locates the body in the sphere of the inner self.[829]A third argument stems from the protection of personal data and privacy. Since a transfer of human tissue also entails the transfer of personal information (genetic data), and in Italy and Europe the processing of genetic data is regulated by a particularly restrictive legal regime which has as characteristic the paradigm of the non-commercialization, then it would be hard, on the basis of the notion of personalistic public order, to consider non-gratuitous contracts as valid.[830] Finally, from the point of view of

[825] Article 3.2.c.
[826] Article 21.
[827] See fn. 497 above.
[828] See subsection 17.5.2.
[829] See subsection 10.2.3 above.
[830] See subsection 10.2.4 above.

the negative consequences of delegating to the market the collection of human tissue, it has been sustained that it is goes against the logic of altruism and solidarity to delegate to the market the collection of human tissue because it would cause a discriminatory effect among social classes and because the State should be the main provider of health services.[831] For the aforementioned arguments, Italian scholars have argued that the transfer of human body parts should be based upon the gift paradigm and not the contract paradigm.[832]

Under English law, the debate around the limits to the validity of contracts on human tissue revolves around two lines of arguments: the existence of property rights on human tissue and the scope of application of the principle of human dignity for the determination of such limits. Regarding the first line of arguments, the HTAct prohibits to give or receive a reward for material (including tissue) destined to transplantation.[833] However, the HTAct excepts material that is subject of property because of the application of human skill. In the common law systems, there has been a long tradition of considering the human body and its parts as outside the property domain, expressed in the so called "no property rule". However, several exceptions to this rule have been created via case law, one of which is the so-called human skill exception. According to this exception, property on human body parts arises from the application of human skills such as preservation technics. This exception has its origins in the famous Australian case Doodeward v. Spence of 1908. In this case, judge Griffiths CJ argued: "When a person has by the lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it."[834]

From this exception explicitly included in the HTAct, one may argue that non-gratuitous contracts on tissue that has been the object of human skill may be considered valid under English law.

Regarding the second line of arguments, English scholars have distinguished between, at least, two different types of conception of human dignity: human dignity as empowerment and human dignity as constraint.[835] If the conception of human dignity as empowerment is endorsed, one could argue for the validity of non-gratuitous contracts on human tissue. If, on the contrary, the conception of human dignity as constraint (which informs both the CFREU and the Oviedo Convention) were defended, the consequence would be the invalidity of such contracts.

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[831] See subsection 10.2.6 above.
[832] Resta, 2001, p. 57.
[833] See subsection 14.3.4.
[834] Doodeward v Spence (1908) 6 CLR 406. For more case law on the matter see fn. 604.
[835] See subsection 22.3.2 below.

Finally, since non-gratuitous contracts on human tissue have a highly disputed moral content, it remains unclear whether or not the notion of good morals under English law may play a role when deciding the validity of such contracts on human tissue under the heading of public policy of "immoral contracts".

20.5 Limits to the validity of contracts on human tissue between the first recipient and subsequent recipients (e.g. MTA).

Section 20.2 of this chapter explored, from a comparative perspective, contracts on human tissue explicitly allowed or prohibited by the Italian and English legal systems. Section 20.3 discussed the possible applicable limits to all types of contracts, independently of the position of the contractual parties or the gratuity or non-gratuity of the contract. Section 20.4 focused on the limits to validity of non-gratuitous contracts.

The aim of this section is twofold. Firstly, it will discuss, always from a comparative perspective, the limits to the validity of contracts concluded between the first and subsequent recipients. Secondly, it will compare the different clauses included in the models used in the contractual practice in England and Italy.

Regarding the first aim, a few preliminary remarks are needed. In the first place, since the general limits applicable to all contracts have been already profusely addressed, I will no longer discuss them in this section, unless necessary for the understanding of new limits. In the second place, the gratuity or non-gratuity of the contract is not relevant for the determination of the limits of these types of contracts. In Italy and England, the reasons for such irrelevance stem, respectively, from the scope of application of the prohibition of financial gain and from the work and skill exception to the common law non-property rule. In what pertains to the scope of application of the prohibition of financial gain included in the CFREU and the Oviedo Convention, it is clear that it is aimed at prohibiting commercial exploitation of the human body and its parts in its natural state.[836] With regard to the work and skill exception, the same consideration applies. If a person, by virtue of the application of a human skill modifies a human body part, it can become the object of property and therefore transferred to other parties in exchange of economic consideration.[837] In the case of contracts between the first and subsequent recipients, the first recipients must have had modified the tissue in order to store it, for example by fixing it in paraffin blocks. For this reason, these types of contracts will always fall outside the scope of the prohibition of financial gain and the no-property rule of the common law. Thirdly, all the consideration related to consent for the removal of human tissue do not apply in

[836] See section 9.2.
[837] See fn. 604 above.

these types of contracts since the first recipient must have had obtained the consent for the removal from the original source of the tissue.

For the aforementioned reasons, the limits to the validity of these contracts will essentially stem from the requirements of consent for the storage and use of human tissue and the data associated to it.

Therefore, the first question that must be answered in order to determine the validity of contracts is whether or not the consent of the original source of the tissue is necessary for the transfer by the first recipient to subsequent recipients.

In this regard, the GDPR provides a framework of analysis applicable to both Italy and England. According to the GDPR, when the further processing of the data associated to a tissue sample is done for achieving purposes in the public interest or scientific purposes, a new consent from the data-tissue source is no longer necessary (Article 5(1)b GDPR). However, two conditions must be met in order to use the data without a new consent. Firstly, technical and organizational safeguards that respect the principle of data minimisation must be included for the protection of the rights of the first transferor of the tissue (Article 89(1)), e.g. pseudonymisation measures. These safeguards are to be in place by each Member State. Secondly, it must be assessed whether anonymous data cannot be used instead (Recital 156 GDPR). Particularly, in relation to genetic data, the GDPR includes a specific provision that prescribes these type of data can be further processed for research purposes without the need of a new consent (Article 9.2 GDPR).

What should be understood then for scientific purposes? This term must be interpreted, according to the GDPR, in a broad sense to include commercial research. In fact, Recital 159 prescribes that "(w)here personal data are processed for scientific research purposes, this Regulation should also apply to that processing. For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research".

However, what happens if the purpose of a contract between the first and subsequent recipients does not fall within the exceptions to consent of the GDPR? It seems logical to assume two possible scenarios. Either the first transferor of the tissue has explicitly consented to further transfers, or either she has not. In the first case, the subsequent transfers would be valid, in the second case such transfers would not be legally possible.

From the tenor of the aforementioned considerations it can be distilled a first limit applicable to contracts between the first and subsequent recipients in both the Italian and English legal systems: when the first recipient intends to transfer

human tissue to further recipients for purposes different than the ones exempted in the GDPR, it is always necessary to obtain the consent of the first transferor.

Regarding the national limits to these types of contracts there are some formal and substantial differences between England and Italy. A first formal difference stems from the fact that, unlike Italy, England has a specific statute aimed at regulating the use of human tissue (the HTAct). Although the HTAct is built around the idea of consent, it provides a series of exceptions to the consent of the first transferor. One of these exceptions prescribes, in line with the GDPR, that consent is not necessary for the use and storage of relevant material that come from living persons for the purposes of research in connection with disorders or the functioning of the human body (section 1(4)(9) HTAct). However, for this exception to apply two further requirements must be met: 1) Research must be approved by a recognized research ethics committee (REC) according to the regulations made by the Secretary of State. However, according to the Code of Practice E, a university ethics committee does not qualify, for the purposes of the exception, as a recognized REC. 2) Research must be carried out in circumstances such that the person carrying it out is not in possession, and not likely to come in possession of information from the original source of the tissue.[838]

The Italian legal system is more severe in the regulation and does not provide for a similar exception. On the contrary, there are further requirements for the use of genetic data. In fact, according the Genetic Data Authorization,[839] genetic data can only be used if the person has previously expressed her written consent (Article 6). Nonetheless, similarly to England, this Authorization prescribes that the use of non-anonymous data must be preceded by the preparation to a research project that includes the necessary measures to ensure the confidentiality of the information of the original transferor of the issue (Article 4.2).[840] Additionally, for the use non-anonymous data and tissue samples, in the same line as the GDPR, it is necessary to first assess whether or not anonymous data and tissue cannot be used instead (Article 3.1 Genetic Data Authorization).[841]

From the aforementioned considerations a first difference in the limits to the validity of contracts can be derived. While in England, the first recipient could further transfer the tissue to subsequent recipients without the consent of the original source (first transferor) for the purposes excepted in the HTAct, in Italy

[838] See fn. 575 above.
[839] See fn. 164 above.
[840] See subsection 3.5.1.
[841] Ibid.

consent will always be necessary for such transfers and for all purposes. In England, for any other purposes, consent will also be necessary.

Although the legislation on this matter seems to be more demanding in Italy, the Data Protection Act in England provides an additional protection mechanism for the rights of the original transferor of the tissue. According to section 19(2) of this Act, processing is not according to Article 89(1) GDPR, if it is likely to cause to the data subject substantial distress or damage. For this reason, contracts between the first recipient and subsequent recipients find in this article a further limitation.

Finally, regarding the different clauses included in the different MTAs in Italy and England, two main differences can be identified. Firstly, Italian MTAs, surprisingly, are more prone to recognize property rights on human tissue, albeit the contract clauses prohibit any financial gain from the tissue transfers.[842] Secondly, strikingly, English MTAs include several clauses with references to the consent of the original transferor of the tissue and the protection of her data rights.[843] In Italy, such clauses are conspicuously absent.[844]

[842] See chapter 11.
[843] See chapter 18 above.
[844] See fn. 842 above.

Part 6

THIS BOOK'S POSITION

21

Chapter 21

The validity of gratuitous contracts on human tissue concluded between the first transferor and the first recipient

PART 6 THIS BOOK'S POSITION

CHAPTER 21 The validity of gratuitous contracts on human tissue concluded between the first transferor and the first recipient

21.1 Introduction

The aim of this chapter is to approach, from a theoretical perspective, two debated issues related to gratuitous contracts between the first transferor and the first recipient. The first issue is the scope and form of consent to the transfer and use of human tissue for research. Section 21.2 will briefly describe the possible types of consent in order to assess what should be understood for valid consent. The second issue is the extent of protection that should be afforded to the person's data in the use of human tissue. For this purpose, section 21.3 will firstly describe the processes of anonymization and codification of tissue samples. Secondly, section 21.3 will discuss what is the best possible way to protect the person's privacy, data and autonomy. Finally, section 21.4 presents a number of recommendations and suggestions for legislative reform.

21.2 Consent

Consent, a safeguard for the person's autonomy, is the ethical justification for the interventions on the human body in the spheres of medical treatment and research. Even though consent has been more frequently associated with the doctor-patient relationship, it is also one of the essential requirements for the legitimacy of research on human tissue.

References to the need for consent for research on human tissue are present in several legal sources:

- Article 5 of the Universal Declaration on the Human Genome 1997 and Human Rights: "(a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law. (b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest." [845]
- Article 10 of The Council of Europe Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin: "1. Biological materials should be obtained for research in accordance with the provisions of this chapter. 2. Information

[845] Declaration on the Human Genome 1997. See fn. 158.

and consent or authorisation to obtain such materials should be as specific as possible with regard to any foreseen research uses and the choices available in that respect." [846]

- Article 13 of the Tissue and Cells Directive 2004: "1. The procurement of human tissues or cells shall be authorised only after all mandatory consent or authorisation requirements in force in the Member State concerned have been met." [847]
- Article 5 of the Oviedo Convention: "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it (…)."[848]

The aforementioned legislative provisions and the comments of scholars thereto do not provide a clear definition of what should be understood for consent to research on human tissue. It is equally hard to find a definition in the legal literature on this matter. However, nothing stands in the way of extending -with the necessary adaptations- the notion of consent used in the sphere of medical treatment to the one of research on human tissue. Thus, consent could be understood as the process of communicating the person's decision(s) in relation to the use of her tissue for research, after she has been sufficiently and intelligibly informed of the nature and consequences of research on her tissue.

Notwithstanding the generalized unanimity on the necessity to seek consent prior to the use of human tissue for research, the issue of how wide the scope of consent should be in order to legitimize research is still a major debate among scholars.

There is consensus in the literature on that consent may either be explicit, implicit, or tacit: "Explicit consent is an expressed consent, consisting of some overt communication of agreement", [849] implicit consent refers to the one that is bound to the one given for general diagnosis and clinical care,[850] and tacit consent refers to the consent that is expressed passively or silently, by failing to dissent.

It is maintained that consent can also be broad, if it is given once and for all types of research on the tissue, or specific, if given for a specific study. Legal scholars are divided between those who consider that broad consent is enough to

[846] Council of Europe, *Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin.* (Hereafter Recommendation on research on biological materials on human origin 2006).
[847] See fn. 462 above.
[848] See fn. 25 above.
[849] Price, 2014, p. 104.
[850] Winterton MP, HC Deb 15 January 2004, vol 416 col 990: 'Where tissue is taken from living patients, some purposes are so bound up with general diagnosis and clinical care that the consent the patient gives to the procedure itself can be regarded as consent for other purposes'

legitimize research and those who consider that it does not suffice for safeguarding the subject's autonomy.

In favour of broad consent it has been argued that:

- Scientific research would be restricted if it is necessary to ask for a specific consent for each and every act that it entails;[851]
- What makes consent an ethically substantial requirement is not the amount of given information, but it to be genuine, that is to say, that the person decides free of duress or coercion;[852]
- The very notion of a fully informed consent is an unreachable ideal;[853]
- In so far as the information associated to the tissue sample is managed safely, there is no reason to rule out broad consent as a valid one.[854]

The critics of broad consent have maintained that:

- Broad consent is incompatible with the necessity to fully inform the source of the tissue sample about the purposes and risks of the research since those purposes are still unknown (even for the researchers) at the moment of asking for the consent;[855]
- The codification of the information associated with the tissue sample does not guarantee in all cases its safe handling;[856]
- Supporters of broad consent tend to confuse autonomy with freedom. Even though one is free to waive all kinds of consents, it does not follow that a given broad consent will respect the person´s autonomy;[857]
- It often occurs that when human tissue is taken for the purposes of a specific research, it still can be used for further and different studies and experiments. In this case, it is advisable to ask the person two different consents. One for the use of his sample for the research for which it was originally taken, and a second one for the storage and use of her sample for new studies.[858]

Furthermore, some arguments have been given to find a middle ground between these two opposed views on consent. Some have proposed to combine broad consent with a specific one for those kinds of studies that are particularly

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[851] Martín Uranga et al., 2005, p. 38.
[852] NCB Guidelines, 1995, p. 45. <http://nuffieldbioethics.org/wp-content/uploads/2014/07/Human-tissue.pdf> accessed 4 November 2019.
[853] Ibid.
[854] Hofmann, 2009, p. 125.
[855] National Bioethics Advisory Commission, *Research Involving uman Biological Materials: ethical issues and policy guidance (Report and Recommendations),* 1999 (thereafter NBAC Report 1999), p. 65. <https://bioethicsarchive.georgetown.edu/nbac/hbm.pdf> accessed 16 December 2019.
[856] Hoffman, 2009, p. 126.
[857] Ibid.
[858] MRC Guidelines, 2001 p. 15.

sensitive by its nature e.g., research on ethnic groups or behavioural studies.[859] It has also been maintained that an ethics committee should be in charge of supervising and authorizing these types of research in order to ask for a specific consent when the nature of the research demands it as a safeguard for the person´s rights. In addition, it has been suggested that trusting a third party outside the research team with the identifying codes of the sample would allow the person that gave an initial broad consent to inquire about the types of research that are being carried out on her tissue.

This book argues that the validity of informed consent depends on the autonomy of the person and its genuine communication. Therefore, it would be acceptable to allow broad consent for future and still undetermined studies, insofar as the individual´s rights on her tissue are still protected while conducting research, e.g., the confidentiality of data associated to the tissue sample, the right to not to know and the obligation of the researchers to communicate to the aforementioned delegated third party the types of studies that are being carried out on tissue samples.[860]

However, it should be underlined that a broad consent for all types of research is not ethically acceptable. It should be up to the donor to decide, accordingly to the modality of the research and interests involved in it, the type of consent that she is willing to give:[861]

- Specific consent for one particular research project;
- Specific consent for a particular research project with the possibility open to the researchers of asking for new consent in case they intend to carry it out on a different type of research;
- Consent partially restricted to specific types of research, e.g., research on cancer;
- Broad consent for present and future research for any kind of research with an anonymized or codified sample and;
- Broad consent for present and future research with an identified sample.

Independently of the type of consent, in order for consent to be considered valid, it is of vital importance that the person receives all the necessary and appropriate information. Thus, researchers should inform, when possible, and depending on the type of research, the following aspects:

[859] Martín Uranga et al., 2005,, p. 40.
[860] Ibid. p. 39.
[861] See Casabona, 2011, p. 1141 and the World Health Organization, Guidelines for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research, 2000 ('Thereafter WHO Guideline 2000), p. 3. <http://www.who.int/reproductivehealth/topics/ethics/human_tissue_use.pdf?ua=1> last accessed 2 November 2019.

1) Regarding the tissue samples: a) the voluntary character of the extraction and further analysis on the tissue sample; b) the number and quality of the samples that will be obtained and c) the intended use and disposal of the sample during and after the research (e.g. transfer to third parties, storage for future research, destruction of the sample once the study has ended, human implantation).
2) Regarding the risks of research: a) the risks of the procedure and b) the risks that the handling of the information involves;
3) Regarding the information associated to the tissue samples: a) the information that could be obtained from the analysis and the methods to handle it (whether or not the tissue samples will be codified or anonymized); b) the intended duration of the use and storage of the obtained data; c) the confidentiality of the information; d) the importance for relatives of the possible outcome of the analysis on the sample (e.g, in the case of genetic research); e) who will be able to access that information (relatives, researchers, the persons itself, third parties) and; f) in case of unexpected findings the right of the person to know and to not know about them;
4) The availability of genetic counselling;
5) The potential commercial use of the sample and the data associated to it or to the research results, and the research sponsor.

The aforementioned information should be provided to the person to ensure the validity of the consent and to protect the rights and interests of the weaker party (the source of the tissue sample). Arguably, the validity of consent could be challenged it one of these aspects has not been sufficiently informed. However, the analysis of the validity of the consent should be done on a case-by-case basis.

Furthermore, under a contractual model for the regulation of rights and duties on human tissue, the aforementioned information could be incorporated to the contract in the form of contractual clauses to provide legal certainty and for the protection of all the parties involved.

21.3 Identification, codification and anonymization of samples and the protection of fundamental rights

Identification, codification and anonymization are concepts that refer to the degree of association of the data contained in a human tissue sample with the identity of the original source of the tissue.

Identified samples are those directly related to the person and her personal information (e.g., name and ID). This type of tissue sample is the one that presents greater risks to the privacy of the person from whom the tissue has been removed.

Codified or pseudonymised samples are those that even though they are not directly linked with the source, can be associated again with it via a decoding process. Those tissue samples are also knows as identifiable or re-identified because notwithstanding the fact that by means of attributing a code to the sample, the personal information of the source is unknown to the researchers, it can be re-linked again with the donor´s information by breaking the assigned code. The process of codification can be simple or double. When the codification is simple, the code remains in the hands of the researcher or the centre where the samples are being stored. When the codification is double, a second code is entrusted to a third party. The latter grants a major level of safety to the information because in order to decode the information it will be necessary to be simultaneously in possession of the two codes.

Anonymized samples are those who cannot be linked anymore the personal information of the donor, even though they were at first linked to it.

Anonymous samples are those that were obtained from the beginning without collecting the donor´s personal information, for example when those where the conditions agreed when donating a sample for research.

Although it would seem that the last two types of samples would seem to protect better the confidentiality of the information and the privacy of the person, these type of samples are in many cases of little value for research since they do not allow the comparison of the results of the research with the actual condition of the transferor of the tissue (retroactive validation and demonstration of reproducibility).[862]

In my opinion, the aforementioned definitions are useful to identify the different types of processes applied to the tissue samples in order to unlink the personal information of the donor from the donor itself. Other definitions on the matter could also serve the same purpose but are somehow vague or imprecise. It is the case of the one given on personal data by the Council of Europe: "For the purposes of this recommendation: -the expression "personal data" covers any information relating to an identified or identifiable individual. An individual shall not be regarded as "identifiable" if identification requires an unreasonable amount of time and manpower. In cases where the individual is not identifiable, the data are referred to as anonymous".[863]

Since the amount of time would vary depending on whether or not it is an expert or a layman that is seeking the identification of the person, it remains unclear

[862] Helgesson et al, 2007, p. 974.
[863] Council of Europe, *Recommendation* (97) 5 of the Committee of Ministers on the Protection of Medical Data, 1997 ('Thereafter Recommendation for the Protection of Medical Data 1997). Article 1.

what should be understood as "unreasonable amount of time and manpower". Furthermore, codification (simple or double) and anonymization do not guarantee completely the safety of the information. On the one hand, the security mechanisms could easily be broken by a systems and encryption expert,[864] and on the other hand, it is also possible that the donor could be identified by the nature of the research itself, even if the tissue sample has been anonymized, e.g., in genetic research.[865]

Furthermore, it has been argued that the legal use of the concept of anonymization of human tissue is a rhetoric way of assigning research on human tissue an ethical neutrality: "Two rhetorical trade-offs are put forward to create a convincing image of the axiological neutrality of the operation which make human biological samples available to scientific research and the world of industry. The first consists in associating the cancellation of all individual interest with the removal of sensitive information. The second consists in the idea that the subject´s lack of control over the human tissue derives from the (alleged) loss of a subjective interest in the informational content of her tissue, i.e. in defining these as res derelictae".[866]

The latter is perhaps the most important problem when dealing with anonymized samples since it poses the question of whether or not the process of anonymization protects the confidentiality of the data.[867] However, other major difficulties arise when analysing the practical implication of the codification and anonymization processes:

- To what extent is it possible for the person to withdraw her consent for research or to ask for the destruction of her tissue sample when it has been codified or anonymized? [868]
- If as a result of the research carried out on the sample, unexpected information about the health of the person is found, could these findings

[864] Tallacchini, 2005, p, 163.
[865] O´Brien, 2009, p. 99. "It is becoming increasingly evident that anonymization of composite genotype data or even clinical data is virtually impossible, since combination of phenotypic and genotypic character can be readily matched to any individual research participant. For example, Lin et al. demonstrated that as few as 30 SNPs will unequivocally identify a single person in a large study population. (…) Absolute anonymity is basically unachievable in these large cohort population databases, tempting misuse by people with scurrilous motives".
[866] Tallacchini, 2005, p. 158.
[867] Declaration on the Human Genome 1997. Art. 7. "Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law."
[868] Bellivier & Noiville, 2009, p. 66: "Le droit de retrait n'est pas en pratique possible que si les données n'ont pas été anonymisées ou si l'anonimisation est réversible; en fin, et plus fondamentalement, certains contestant la légitimé même du droit d´effacement: toute une recherché pourrait-elle être affecté par le retrait intempestif et inconditionnel d'un sujet qui, par exemple, posséderait des caractéristiques uniques?"

be communicated to her, independently of the type of sample that has been used?
- Since some particular types of research would be seriously limited in case the samples are codified or anonymized, how to reconcile the conflict between the protection of the data confidentiality and the scientific progress?
- Is it possible to determine a specific process on the samples as the best suitable for all kinds of research or is it necessary to analyse every particular case in order to ascertain which one is the appropriate one for protecting the confidentiality of the data?

The potential conflictive situations relating to the confidentiality of the data can be found not only within the sphere of contractual relations (insurance and employment contracts), but also at the familial and societal level and within the person´s private sphere since she could want to know (or not) the outcome of the research on her sample. It has been argued that these latent conflicts can be divided in six categories:[869]

The first conflict arises when the person decides to not be informed of the unexpected findings on her health as a result of the research carried out on her sample. The researchers face then two dilemmas. Firstly, whether to inform or not the person that she is the carrier of a disease. If the researcher chose not to disclose the information, they would protect the confidentiality of the information but could possibly also harm a legal right of the original transferor of the tissue (to whom they do not have a direct legal duty) that could have an interest in knowing that information.

A second dilemma manifests itself when the member of the consanguineous family is a healthy carrier of the same genetic anomaly and, as a consequence, could have an interest in such information.

Thirdly, certain members of the family in law, or the partner of the original transferor of the tissue could have an interest in the information, e.g. because in so far as a future child is likely to inherit the same genetic anomalies.

Furthermore, the parties involved in a contractual relationship (employment or insurance contract) could have an interest, legitimate or not, in knowing the medical data associated to the tissue sample.

In addition, collective societal interests could require the use of the genetic data, for example, to identify the author of a crime.

[869] De Sola, 1994, p. 181.

Finally, medical research depends strongly on the knowledge of the data concerning individuals carrying genetic deceases: how to balance scientific progress with the protection of the person´s privacy?

It is certain that the degree of conflict in the aforementioned categories will vary depending on the type of sample (identified, codified or anonymous) that has been used for the research. I will therefore analyse the aforementioned latent conflicts to try to find a possible solution to problems posed in this section.

One of the main arguments against anonymization is that it harms the person´s autonomy because she loses control over the samples once they have been anonymized.[870] Arguably, the issue of autonomy should be analysed *ex ante* and not *ex post* the extraction of the tissue sample. The donor is not threatened in her autonomy if the election of anonymizing her tissue sample is the result of an informed and conscious decision. If the sample was initially obtained for the purposes or research the decision of anonymizing the sample should be taken prior to its removal. However, if the sample was initially taken as a consequence of a medical treatment and it is later on intended to be used in research it would be advisable to look for the consent of the original transferor, and if that is not possible, then rendering the sample completely anonymous would be the best possible practice.

From an ethical point of view, nothing stands in the way of the donors' decision to not knowing the results of the research.[871] However, if the person expresses her desire of knowing the research´s outcome it will be unethical to anonymize the sample, because in this case her autonomy would be in fact harmed. In this situation, encoding the sample would protect both the person´s right to know and the confidentiality of the data associated to the sample. The use of an identified sample for research is most of the times difficult to accept from an ethical point of view for the high risks that it present to the privacy of the donor, [872] but should it remain identified, it is up to the researcher to justify the reasons why research cannot be carried out on a coded or anonymous sample.[873]

In addition, the degree of conflict when a member of the family or any other third party with a legitimate interest wants to know the research findings will also vary depending on the type of sample. Undoubtedly, when the material is

[870] Helgesson, 2007, p. 974.
[871] Oviedo Convention: "Article 10.2 Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed."
[872] Universal Declaration on Human Genetic Data 2003 art. 14: "c. Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples."
[873] Yann et al., 2005, p. 4

anonymous or anonymized, not even the donor will have access to the research results, and as a consequence it would be illogical to suppose that a third party could or should be able to access them. The same can be said when the donor has expressed her desire to not know. However, that is not the case when dealing with identified samples and the person has stated her desire to know the results.

Moreover, it is clear that certain types of research would have their chances for success limited if they were carried on anonymous or anonymized samples.[874] However, scientific progress is not a mandatory goal. A slower rhythm in the development of science is more desirable than one that threatens essential ethical and societal values.

Taking into account the aforementioned consideration it would be desirable to allow the person to withdraw her consent when research is carried out on identified samples since they still contain the personal information of the donor and as a consequence research on her materials could be considered as a form of experimentation on humans.[875]

In the case of anonymous or anonymized samples the right to withdraw consent is in practice impossible since they have been completely unlinked from the donor's personal information.

Furthermore, to protect the person's autonomy it is necessary to grant her the possibility of choosing which kind of process will be applied on her sample (e.g. codification or complete anonymization), even if this undermines scientific progress. The donor is the only person legitimized to decide whether her personal information should remain associated to her samples or not. If asking for her consent is not possible in practice, it would be desirable to irreversibly anonymize her sample in order to protect the security and confidentiality of the data. This could be the case of samples that have been taken and stored, at first, for diagnostic purposes. If it were no longer possible to trace the person from whom the sample was taken, it would be desirable to anonymize the sample for its use in research.

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[874] Ibid. p. 4: "Anonymized samples radically reduce the value of the patient´s participation in PGx research. Subsequent to anonymization, it will no longer be possible to obtain additional information from the patient´s medical file. Once the trial is completed, for example, this constraint prevents the researcher from verifying if the observed responses to medication during research combined with other research results are due to genomic or genetic variations, or due to other factors. Anonymized samples will be useful for research aimed at generating assumptions, but less interesting in the case of pharmacogenetics clinical trials whose goal is to support label claims".

[875] Tallacchini, 2005, p. 157.

Even if it is true that anonymization does not completely protect the individual from the possible risks associated with the research, it is also true that it seems to be the best possible option to safeguard the transferor's rights[876].

Finally, many of the described conflicts could be avoided if contractual clauses are included to determine the level of protection of the sample. It would be the original transferor of the tissue, the one called to decide, *ab initio*, the level of identification of her samples.

21.4 Recommendations

In relation to the matters covered by this chapter, this book proposes the following recommendations:

1) It is desirable to regulate, via contract law legislative provisions, the tissue transfers between the first transferor and the first recipient.
2) This regulation should place on the first recipient, prior the conclusion of the contract, a clear set of information duties towards the first transferor of the tissue.
3) The information that should be provided to the first transferor includes the following:

    - Regarding the **tissue samples**: a) the voluntary character of the extraction and further analysis on the tissue sample; b) the number and quality of the samples that will be obtained and c) the intended use and disposal of the sample during and after the research (e.g. transfer to third parties, storage for future research, destruction of the sample once the study has ended, human implantation).
    - Regarding the **risks of research**: a) the risks of the procedure and b) the risks that the handling of the information involves.
    - Regarding the **information associated** to the tissue samples: a) the information that could be obtained from the analysis and the methods to handle it (whether or not the tissue samples will be codified or anonymized); b) the intended duration of the use and storage of the obtained data; c) the confidentiality of the information; d) the importance for relatives of the possible outcome of the analysis on the sample (e.g, in the case of genetic research); e) who will be able to access that information (relatives, researchers, the persons itself, third parties) and; f) in case of unexpected findings the right of the person to know and to not know about them.

[876] Ibid: "However, the anonymization of the data and samples should not be used as an excuse for researchers to simplify ethical or legal hurdles or to neglect the participant's rights to self-determination".

- The potential **commercial use** of the sample and the data associated to it or to the research results, and the research sponsor.
- The availability of **genetic counselling**.

4) Article 13 GDPR, which already includes some of the items listed above, should be expanded to include them all.
5) At least the following items of the list above should also be included as mandatory contractual clauses for the transfer of tissue: a) the number and quality of the samples that will be obtained; b) the intended use and disposal of the sample during and after the research; c) the intended duration of the use and storage of the obtained data; d) the confidentiality of the information and who will be able to access that information; e) the potential commercial use of the sample and the data.
6) The proposed contract law regulation should include mandatory and default rules for contracts between the first transferor and first recipient.
7) A necessary mandatory rule should prescribe that prior to the conclusion of the contract, the first transferor must assess whether or not anonymous information can be used instead of personal information.
8) A possible default rule should indicate that, once it has been established that anonymous information cannot be used, the sample should be codified or pseudoanonymized.
9) The proposed regulation should allow the first transferor and the first recipient to deviate from the previous rule.
10) The first transferor of the tissue should be free to decide, once it has received all the appropriate information, whether to give a specific or a broad consent for the research on her tissue.

22

Chapter 22

The validity of non-gratuitous contracts on human tissue concluded between the first transferor and the first recipient

CHAPTER 22 The validity of non-gratuitous contracts on human tissue concluded between the first transferor and the first recipient[877]

22.1 Introduction

The possibility of allowing non-gratuitous contracts[878] on human tissue for research purposes has been an issue of much debate among bioethicists, legal scholars and economists.[879] The range of views in this debate can be clustered in two sets of arguments against and in favour of the conclusion of such contracts. The first set relates to a legal-ethical debate that can be formulated in terms of the tension between autonomy and paternalism: are individuals formally and substantively free to sell their tissue or, on the contrary, should the State and the law intervene in order to prevent individuals from selling their tissue as this is considered to be prejudicial to their own interests?

On the one hand, the main argument in favour of allowing the sale of human tissue has its foundation on a line of thought that closely links autonomy, freedom and freedom of contract. According to this idea, the sale of human tissue is an activity that falls within the realm of individual autonomy and should not be prohibited on the grounds of an external morality. Individuals should be free to take decisions to build and develop their life project according to their own sense of morality.

On the other hand, the arguments against the sale of human tissue have a strong moral component and entail, to greater or lesser degree, a form of legal paternalism. Broadly speaking, most of the arguments against the sale of human tissue for research are based on one or more of the following considerations: 1) The people who have the strongest interest in selling their tissue are the economically disadvantaged ones. One may argue that the sale of tissue by an individual in financial distress is not based on freedom, but on (economic) coercion. And one may argue that allowing such sales increases the inequality between the rich and the poor. 2) Economic remuneration for human tissue commodifies the person and is contrary to human dignity: therefore, a market for human tissue degrades the person. 3) The market logic in the transfer of human tissue casts out the principles of altruism and solidarity, which would be safeguarded by a system that prohibits the sale of tissue and only allows tissue donations or other types of gratuitous transfer of tissue.

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[877] Some parts of this Chapter have been previously published in Santamaria, 2017, p. 195-214.
[878] Scholarly literature on the matter does not speak often of non-gratuitous contracts on human tissue. Instead, authors refer to the sale of human tissue. This book prefers the terms non-gratuitous contracts because this term may include contracts performed in exchange of economic remuneration other than sales. However, because the term 'sale' is commonly used in scholarly literature, this Chapter also uses it when referring to the arguments against and in favour of non-gratuitous contracts on human tissue for the purposes of research.
[879] For an overview of this debate see Korobkin, 2007, p. 45 with further references.

The second set of arguments concerns the practical and economic advantages and disadvantages of allowing markets for human tissue (e.g. whether or not a market for human tissue enhances research, or whether or not such a market increases the offer of human tissue). Since this book is not primarily concerned with the economic efficiency of contracts but with their validity, the arguments against and in favour non-gratuitous contracts based on these practical and economic advantages will not be discussed.

The aim of this chapter is three-fold. Firstly, this chapter discusses whether or not the arguments against the sale of human tissue justify intervention on the person's sphere of action in the form of legal restrictions of such sales. Secondly, this chapter argues that although certain forms of paternalistic intervention may be justified to protect the person's rights, prohibiting the sale of human tissue is detrimental to the person's autonomy. Finally, this chapter suggests that contract law and contracts, – as means of self-regulation and governance together with the use of some forms of soft paternalistic intervention – may protect the interest and rights of the person's transferring human tissue for research better than a strict ban of such sales.

The following section (22.2) of this chapter firstly discusses briefly the idea of autonomy as self-authorship and its relation to value-pluralism. Secondly, it describes the different forms that paternalism can take and their legal-ethical limits. Section 22.3 draws on the work of Fateh-Moghadam and Gutmann[880] in order to assess whether or not the arguments against the sale of human tissue for research fall within one of the different forms of paternalism (hard or soft) and inquires whether these arguments sufficiently justify the legal intervention on the person's sphere of action. Section 22.4 discusses to what extent contract law and contracts as means of governance can play a role in alleviating the tension between autonomy and paternalism and submits that allowing the sale and other non-gratuitous contracts on human tissue may provide a strengthened protection to the rights of the first transferor of the tissue (e.g. the seller). For this purpose, the same section addresses the theory of contract governance proposed by Möslein and Riesenhuber[881] and analyses and compares three different cases of contracts or other acts concluded by non-state actors related to the governance of research, including a case of governance through non-gratuitous contracts. Section 22.5 draws a number of conclusions and presents some recommendations and suggestions for legislative reform.

[880] Fateh-Moghadam & Gutmann, 2014, p. 383.
[881] Möslein & Riesenhuber, 2009, p. 248.

22.2 Autonomy and paternalism

22.2.1 Autonomy as self-authorship

Raz's understanding of autonomy revolves around the idea "(…) that people should make their own lives. The autonomous person is a (part) author of his own life. The ideal of personal autonomy is the vision of people controlling, to some degree, their own destiny, fashioning through successive decisions thought their lives".[882] In this sense, autonomy is understood as self-creation or self-authorship. If one could evoke an image to materialize such ideal, M.C. Escher's "Drawing hands" famous lithography would fit this purpose. In this lithography, two hands emerge from a sheet of paper and mutually draw each other. The sheet of paper rests on another (unknown) surface. In Escher's lithography, and in the idea of autonomy, the creative subject is at the same time the object of the creation. The act of creation is –according to this ideal– a circular, dynamic and evolving process that draws on personal choices and background conditions. In the "drawing hands", the sheet of paper would represent personal background conditions and the range of options available to the person, i.e. the frame for self-creation.

For a person to be the author of his own life, Raz identifies what he calls the conditions of autonomy: appropriate mental abilities, independence and an adequate range of options.[883] Appropriate mental abilities include "minimum rationality, the ability to comprehend the means required to realize his goals, the mental faculties necessary to plan actions" among others.[884] Independence implies freedom from coercion or manipulation by others. An adequate range of options implies that these options are morally acceptable.

Since the exercise of autonomy presupposes the existence of an adequate range of morally acceptable options (often incompatible with each other), Raz derives the necessity of value-pluralism: "Excellence in the pursuit of goods involves possession of appropriate virtues. Where the goods are varied in character, so that they display varied merits or advantages, their successful pursuit requires different virtues. The existence of more goods than can be chosen by one person, which are of widely different character, speaks of the existence of more virtues than can be perfected by one person. It tells of the existence of value-pluralism".[885] Raz's construction of value-pluralism is based on a monist commitment to autonomy. However, value-pluralism can also be advocated from a free-standing position (foundational value pluralism).[886] According to Dagan,

[882] Raz, 1988, p. 369.
[883] Ibid. p. 372.
[884] Ibid.
[885] Ibid. p. 398-399.
[886] On foundational value pluralism see Dagan, 2012, p. 1409 and Dagan, 2013, p. 19. For an analysis of Dagan's proposal see Gutmann, 2013, p. 55.

although "(…) foundational value pluralism hesitates to give a priori dominance to any value, including autonomy" (…) "there are reasons to believe that the practical prescriptions that "autonomy based value pluralism and foundational pluralism will offer law will largely converge."[887]

One may argue that, independently of whether one endorses one or another kind of these two variants of value-pluralism, a commitment to broaden the spectrum of individual choice arises. In our Escher's lithography example, the effect of value pluralism would be to multiply the number and quality of sheets where the hands can draw. Paternalism, in this regard, causes the opposite effect and restricts the range of possible option and choices.

22.2.2 Hard paternalism

The term paternalism indicates the intervention on the person's sphere of action for her alleged own good, against or without her will or consent.[888] Generally speaking, there are two variants of paternalism: hard paternalism and soft paternalism.

Paternalism is designated as hard when autonomy is not taken into account for the justification of the paternalistic rule: the prohibition of the person's action occurs regardless of whether the person acts autonomously or not. A classic example of legislative hard paternalism is the prohibition of driving a car without a seatbelt. Obviously, paternalism is relative: if a measure that is paternalistic in regard to the protection of the agents against themselves, also protects interests of third parties or society, it would not be paternalistic in regard to the latter.[889] In the example above, the requirement of using a seatbelt can be justified from the perspective of the protection of the car driver and from the perspective of the protection of society as a whole. From the perspective of the car driver, the ban aims at protecting her from self-harm while driving. From the perspective of society, the ban aims at reducing the social costs of driving accidents (e.g. social security cost deriving from medical treatment, incapacity pensions, etc.). In this context, the effects of an action on third parties or society are referred to as externalities. [890] Hard paternalism also occurs when interventions on the person's sphere of action are justified by the alleged incompatibility of the person's action with her self-dignity.[891] When paternalism is concerned with the moral welfare of the individual it is termed moral

[887] Dagan (2012), fn. 886 above, p. 1424-1425.
[888] For similar definitions of paternalism see Fateh-Moghadam & Gutmann (2014) fn 880 above, p. 384; Ogus & Van Boom, 2011, p. 2; Sjöstrand et al., 2013, p. 710; Kronman, 1983, p. 763; Dworking, 1988, p. 121-129.
[889] Kronman (1983) fn. 888 above, p. 764.
[890] Ogus, 2010, p. 61
[891] Fateh-Moghadam & Gutmann (2014) fn. 880 above

paternalism.[892] In this regard, hard paternalism and legal moralism overlap in their scope to limit personal freedom.

The legal justification of hard paternalism is based on the idea that prevention of self-harm justifies coercive legislation.[893] However, from a liberal perspective, hard paternalistic interventions are morally problematic since they raise the questions of to what extent is it justified to impose restrictions on individual autonomy for the wellbeing of the persons whose autonomy is at stake[894] and why such intromissions are permissible in some cases and in some others not.[895]

22.2.3 Soft paternalism

Soft paternalism, also referred as autonomy enhancing,[896] autonomy oriented[897] paternalism in the name of autonomy,[898] or libertarian paternalism[899] is an umbrella term that covers different forms of paternalism that have as common denominator the general aim of respecting personal autonomous decisions. However, the goals and methods of these different kinds of paternalism differ substantially from one another. Fateh-Moghadam and Gutmann have identified four different scenarios of autonomy respecting paternalism:[900] a) classic soft paternalism; b) procedural paternalism; c) endangerment paternalism and; d) libertarian or nudge paternalism.

a) Classic soft paternalism: the intervention aims at hampering non-voluntary self-inflicted harm (e.g. incompetent adults or minors).[901]
b) Procedural paternalism: the intervention is necessary to determine whether the person's conduct is voluntary or not. Once it has been assessed that the person is acting autonomously, the intervention stops. Examples of this form of paternalism are self-harm or self-endangerment caused by error,[902] or in the medical sphere, provisional reanimation in the case of unclear advance directives.[903]

c) Endangerment paternalism: intervention is aimed at preventing non-autonomously self-inflicted harm in a certain context. In these cases, it cannot

[892] Ibid.
[893] Ibid.
[894] Waddams, 2011, p. 145.
[895] Kronman (1983) fn. 888 above p. 765.
[896] Binder & Lades, 2015, p. 3.
[897] B. Fateh-Moghadam & T. Gutmann (2014) fn 880 above.
[898] Sjöstrand et al. (2012) fn. 888 above.
[899] Thaler & Sustein, 2003.
[900] Fateh-Moghadam & Gutmann (2014) fn. 880 above p. 386.
[901] Ibid.
[902] A classic example is the person who has been barred from crossing a bridge because she possible doesn't know that the bridge is rotten.
[903] Fateh-Moghadam & Gutmann (2014) fn. 880 above p. 386.

be proven that the person is acting non-autonomously, but there is a risk that some (unknown) persons may act non-autonomously. Examples of endangerment paternalism are the bans on sex reassignment surgery or organ donation below a certain age.[904]

d) Libertarian or nudge paternalism: intervention is not based on bans but instead focuses on urging or nudging the individual to act in a certain way to maximise the rationality of her preferences. The concept of libertarian paternalism stems from behavioural economics and has been particularly developed by Sunstein and Thaler.[905] According to these scholars, "libertarian paternalism should attempt to steer people's choices in welfare-promoting directions without eliminating freedom of choice"[906] and "should be acceptable to those who are firmly committed to freedom of choice on grounds of either autonomy or welfare".[907] Libertarian paternalism can take two different forms.[908] In its more "intrusive" form, libertarian paternalism "changes the nature of the actual courses of actions available to the agent".[909] In its less intrusive form, libertarian paternalism shapes information about the different options available.[910]

Based on this "phenomenology of soft paternalistic intervention",[911] Fateh-Moghadam and Gutmann advocate for a broader notion of paternalism that includes not only interventions on the person's autonomy, but also on her liberty of action[912] "which every person is fundamentally entitled regardless of her competence".[913] Briefly described, their idea rests on the argument that soft paternalism – just as hard paternalism – is problematic since it may legitimize intervention on persons acting completely autonomously without causing damage to third parties (as in the cases of classic, procedural and endangerment paternalism). Furthermore, in procedural paternalism and endangerment paternalism, "it is accepted that even persons acting fully autonomously are limited temporarily" (procedural paternalism) "or definitively" (endangerment paternalism) "in their liberty of action. (…) For the persons concerned, the difference between hard and soft paternalistic intervention is not qualitative, but, at best, a question of intensity in the intervention or there is no difference at

[904] Ibid.
[905] See for example Sustein, 2015; Schlag, Thaler, & Sunstein, 2010, p. 913; Thaler & Sustein (2003) fn. 899 above; Thaler & Sunstein, 2008; Leonard, 2008, p. 356.
[906] Thaler and Sustein and (2003) fn. 899 above p. 3.
[907] Ibid. p. 4.
[908] Ogus (2010) fn. 888 above p. 62.
[909] Floridi, 2016, p. 1669.
[910] Ibid. p. 1679.
[911] Fateh-Moghadam & Gutmann (2014) fn. 880 above p. 386.
[912] One may wonder if this definition of liberty of action corresponds to what Raz calls autonomy in a primary sense. Raz (1988) fn. 882 above p. 372.
[913] Fateh-Moghadam & Gutmann (2014) fn. 880 above p. 388.

all".[914] An additional argument is given to support a broader notion of paternalism: a broad notion of paternalism shows how the legal attribution of autonomy is itself a problem with paternalism, in the sense that it is contingent and can therefore also be used to justify a hard paternalistic intervention disguised in the costume of soft-paternalism.[915]

Based on these arguments, Fateh-Moghadam and Gutmann have suggested some limits to the aforementioned four cases of soft paternalism. The following section explores these and other possible limits to soft-paternalism.

22.2.4 Limits to soft paternalism

Fateh-Moghadam and Gutmann have suggested that, in what concerns classic paternalism it would be preferable to prioritise the natural will of the incompetent adults or minors.[916] According to them, procedural paternalism constitutes usually a less intrusive form of paternalism with regard to the rights of the persons concerned, when compared to a prohibitory rule or principle, although a legal justification for it is always necessary. With regard to endangerment paternalism, Fateh-Moghadam and Gutmann argue that it is a more questionable form of paternalism since it places a general restriction on the liberty of action of persons that, although might be at risk of acting non-autonomously, cannot be proven in every case to act in such way.[917] For this reason, they suggest that the limits to this form of paternalism should be established on the basis of a proportionality principle, i.e. a test that balances the costs of intervention and the potential costs of learning for the subject. Consequently, "(…) concrete grounds have to be named for believing that consenting individual lacks cognitive and judgement ability, that she is being coerced, or that she is subject to some other relevant absence of will. For this purpose, mere information about the seriousness of the risk and the "objective" irrationality of intended act are not sufficient."[918] Intervention based on endangerment paternalism also stresses one of the paradoxes of autonomy-based paternalism: intervention restricts the same right that it is intended to be protected. This paradox has also been described by Sjörstrand et al. in terms of the contradiction between two different conceptions of autonomy: autonomy as a right and autonomy as a value.[919] Autonomy as a right is described in this regard as occasion focused, in the sense that respect for autonomy implies

[914] Ibid.
[915] Ibid.
[916] Fateh-Moghadam & Gutmann (2014) fn. 880 above p. 390 with further references. For an example of how preference on how the "natural will" of the person could constitute a limit to soft paternalistic interventions see the recent ruling of a Dutch Court in allowing a 12 year old minor to refuse chemotherapy treatment. See case ECLI:NL:RBNHO:2017:3955 available at: https://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:RBNHO:2017:3955.
[917] Fateh-Moghadam & Gutmann (2014) fn. 880 above p. 392.
[918] Ibid. p. 393.
[919] Sjöstrand et al. (2013) fn. 888 above p. 713.

respecting a specific decision in a specific moment in time. On the contrary, the consequentialist tinted understanding of autonomy as a value would justify, in this context, disregarding personal choices under the premise that intervention could lead to enhancing autonomy overall. However, the jump from a right-based conception of autonomy to a value-based one remains problematic from a logical point of view: once cannot promote and restrict autonomy with the same action. If one upholds a right-based notion of autonomy, in cases of high risk it would be preferable to establish "procedural (consultative) solutions" instead of "absolute material bans which are potentially self-harming".[920]

Finally, libertarian paternalism or "nudging" has also been object of criticism. Firstly, because the step from autonomy towards rationality as the guiding principle of libertarian paternalistic intervention is problematic.[921] Individuals should be allowed to take unreasonable decisions since "legal autonomy defines a threshold concept which ensures the minimum conditions under which the individual also has the *liberty to take unreasonable decisions"*.[922]

Secondly because, at least in what concerns its more intrusive form,[923] libertarian paternalism – by changing the nature of the available courses of action for the individual – may result in a de facto forced compliance.[924] In the words of Fioridi "The main problem with ethics by design and structural nudging approaches is that the more they succeed in shaping" a person's behaviour "–the better they implement forms of paternalism–the less they succeed in respecting" that person's "choices (and, when available, the more or less autonomous decisions behind them)."[925]

A similar criticism could be derived from Raz's distinction between autonomy and self-realization.[926] According to Raz, "(s)elf-realization consists in the development to their full extent of all, or all valuable capacities a person possesses."[927] However, a person acting autonomously could reject the path of self-realization, or conversely, a person could reach self-realization by being manipulated into it.[928]

In the following section I will discuss the different types of paternalism and their limits in relation to the different arguments brought against the sale of human tissue for research.

[920] Fateh-Moghadam & Gutmann (2014) fn. 880 above p. 393 with further reference.
[921] Fateh-Moghadam & Gutmann (2014) fn. 880 above p. 394.
[922] Ibid.
[923] This form of libertarian paternalism is also known by the name of structural nudging.
[924] Fioridi (2016) fn. 909 above p. 1677.
[925] Ibid. p. 1678.
[926] Raz (1988), fn. 882 above p. 375.
[927] Ibid.
[928] Ibid.

22.3 The limits to paternalism: arguments against non-gratuitous contracts on human tissue for research

The general prohibition of financial gain[929] from the human body and its parts includes within its scope the sales and other for profit contracts on human tissue. At the European level, Article 3(2)(c) CFREU prescribes that the human body and its parts as such should not be a source of financial gain.[930] Similar prohibitions exist at the supranational level,[931] and in various national states.[932]

The arguments that have been advanced in support of such prohibition are based on at least one of the following considerations: [933]

(a) – Coercion and exploitation: Allowing the sale of human tissue would allow the most economically disadvantaged individuals to sell their tissue. Such sales would be tainted by (economic) coercion because these individuals would sell their tissue in order to obtain (additional) means of subsistence. In face of this possibility, the sale of human tissue would cause an additional pervasive effect that leads to the exploitation of the poor and to increasing the existing gap between the richer and the poorer.[934]

(b) – Commodification and human dignity: There are certain things that should not enter the realm of market rhetoric, e.g. friendship, love and the human body. Allowing the sale of human body parts, in general, and tissue, in particular, commodifies[935] the person and is contrary to human dignity.[936] A market for human tissue degrades the person[937] because her value would be determined by the economic worth of her bodily parts.

(c) – Altruism and solidarity: The principles of altruism and solidarity should guide the transfer of human tissue.[938] A system that follows the market logic and allows for the sale of human tissue would cast out these principles.[939]

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[929] On the prohibition of financial gain see Chapter 9.
[930] Article 3(2)c: "In the fields of medicine and biology, the following must be respected in particular: (…) the prohibition *on making the human body and its parts as such a source of financial gain".*
[931] For example, Article 21 Oviedo Convention. See fn. 25
[932] Besides the national legal systems examined in this book, similar provisions are contained, for example, in The Uniform Anatomical Gift Act 1968 in the U.S. and the Loi n° 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits in France.
[933] For an overview on these arguments see Korkbin (2007), fn. 879 above.
[934] Marway et al., 2014; Kishore, 2005, p. 363 with further references.
[935] Radin, 1996. See also Sharp, 2000, with further references.
[936] On the ways in which human dignity is used in debates about controversial biotechnologies see Caulfield & Brownsword, 2006. For systematizations of the different meanings of dignity see: Schroeder, 2010; Schroeder, 2008; Jacobson, 2009; Ashcroft, 2005, p. 679–682.
[937] For an overview of the degradation argument see Duxbury, 1996, p. 331.
[938] On the different uses of the term solidarity see Gunson, 2009, p. 241.
[939] For an overview of the degradation argument see Mahoney, 2000, p. 163.

An analysis of these three considerations from the perspective of the limits to paternalism necessarily implies the answer of two preliminary questions: Are these considerations paternalistic in nature? And if so, under which category of paternalism do they fall?

According to our working definition of paternalism, the term paternalism indicates an intervention on the person's sphere of action for her alleged own good, against or without her will or consent.[940] Three different requirements are at the core of this definition: (i) the intervention on another person's sphere of action; (ii) for her own good; (iii) without her consent or will. Elements (i) and (iii) are readily found in the prohibition of selling human tissue: the individual is precluded from taking a particular choice (i), and such intervention happens without mediating her consent or will (iii). For this reason, our analysis will focus on the second element (ii). In consideration (a), the intervention aims at protecting individuals from coercion, thus for their wellbeing. In consideration (b) the intervention's intention is to prevent that the person becomes commodified and her human dignity undermined. In consideration (c) the objective of the intervention is concerned with the moral welfare of the individual and society: it is allegedly better –from a moral point of view– to transfer tissue gratuitously and according to the principles of solidarity and altruism than for profit. In (c) the intervention takes the form of moral paternalism.

I have shown how all the considerations in support of the prohibition of selling human tissue are, to a certain extent, paternalistic in nature. Under which category of paternalism do these considerations fall?

One may argue that consideration (a) falls within the scope of endangerment paternalism. The objective of endangerment paternalism interventions is to prevent the materialization of the risk of non-autonomously self-inflicted harm. In consideration (a) the risk is that, because of economic coercion, the person non-autonomously sells human tissue. In this case, no distinction is made between those who allegedly act under coercion and those who, absent coercion, will still sell their tissue. Therefore, from an ethical and legal point of view a first problem arises: why is it justified to impose a general ban that imposes indistinct restrictions on both persons acting autonomously and persons under risk of acting non-autonomously? Two additional questions follow: are economically

[940] The logical structure of paternalism has been described by Floridi in the following terms: "(a) A is informed about B's φ-ing; (b) A could ψ to interfere with B's choice to φ; (c) A is informed about B's φ-ing not improving15 B's or (inclusive or) C's wellbeing, where possibly B = C; (d) A does ψ; (e) A does ψ because16 B's φ-ing does not improve B's or C's well-being; (f) A does ψ without B' s consent". See Floridi (2016) fn. 909 above p. 1674.

disadvantaged persons really at risk of being coerced to sell their tissue? And if so, is a general ban on the sale of human tissue the preferable option to protect their interest or are there less intrusive mechanism to achieve the same or better results?

In considerations (b) and (c) on may argue that the interventions are an example of hard paternalism. In both cases, the interventions' goal is not to protect or enhance the autonomy of the person but to protect or improve her moral status and wellbeing, as such. However, from the point of view of autonomy, why should the law in general, and contract law particularly, be concerned with the moral wellbeing of the individual?

Moreover, additional problems arise from (b) and (c) independently. In (b), the issues to be tackled are whether or not selling human tissue commodifies the person and whether a prohibition of selling human tissue actually prevents commodification. In (c) the query of whether or not the market logic in the sale of human tissue crowds out the principles of altruism and solidarity must be answered.

In the following pages I intend to provide an answer to these questions and I will try to demonstrate why the arguments previously exposed are not sufficient to justify the prohibition of tissue sales. For these purposes, sections 22.3.1, 22.3.2, and 22.3.3 will examine the problems that arise from the abovementioned considerations (a) – coercion, (b) – commodification, and (c) – altruism respectively.

22.3.1. Coercion and exploitation

The supporters of the ban on sales of human tissue argue that these sales might in many cases be tainted by coercion because the most economically disadvantaged individuals will sell their tissue in order to obtain additional means of existence. This would allegedly let the poor be exploited by the rich because the poor would be tempted to assume excessive health risks in exchange of economic remuneration.[941] According to some commentators in favour of prohibiting the sale of human tissue, "(t)o engage in a transaction, does not equate to making a "free autonomous choice", for someone who is poor, the "choice" often can be desperate."[942]

This book submits that in order to assess whether or not economically disadvantaged individuals are coerced into selling their human tissue one must first clarify the content of the term coercion. Raz' definition of coercion proves useful here. If one, for example, considers the proverbial case of a coerced choice

[941] Marway (2014) fn. 934 above p. 581.
[942] Ibid.

– the money or your life –[943] one could distil the core element of coercion: when a person faces the option of either losing her money or losing her life, her choice is restricted to the need of preserving her life. According to Raz, "(t)o the extent that much of a person's life depends on one comprehensive goal, forcing him into a choice where all but one option would involve sacrificing this goal is an attempt to coerce him."[944]

Selling human tissue would only be a coerced choice if it would be the only option in order to maintain the person's life goal(s). Although it is theoretically possible that a person's life goal(s) would depend on such a choice, it is hard to maintain that this should be considered as the general rule. It is of course plausible that individuals selling their tissue might be facing financial hardship, but such economic duress is not in all cases, tantamount to coercion.[945] Not everything that is not an ideal choice is a coerced choice.[946] One might even argue that allowing the sale of human tissue might broaden the pallet of options that a person facing economic problems has. One could also imagine cases whereby a person afflicted by a genetic disease gratuitously transfers her tissue in order to increase her chances of cure or even survival. Should these kinds of transfers also be banned on the grounds of coercion?

However, with regard to the exploitation claim, the argument remains that because of financial hardship, some individuals could be more inclined to sell their tissue and put their health at risk. Is the prohibition of human tissue sales justified on this ground? Firstly, one may say that what this prohibition does is only prohibiting self-exploitation,[947] since economic exploitation is already occurring in the chain of transfers for the use of human tissue. Secondly, as some commentators have already pointed out, "(…) as for the limitation on the permissible risks that tissue sources can undertake for compensation, preventing excessive risk taking by banning payments, instead of regulation of collection procedures and required disclosure of relevant hazards, is a curious strategy."[948]

Therefore, one may argue that the problem of possible health risks connected with the donation or sale of human tissue can be tackled, not by forbidding people to engage in such contracts, but by minimizing the risks and setting up regulations for a better protection of the health of all first transferors of human tissue (independent of whether the transfer is gratuitous or for a remuneration).

[943] Two beautiful and more elaborate examples are given by Raz: The man in the pit and the hounded woman. See Raz (1988) fn. 882 above 374-373.
[944] Ibid. p. 376.
[945] Glitter argues that the doctrine of informed consent is designed to protect the person in cases of financial hardship. Glitter, 2004, p. 312.
[946] Duxbury (1996) fn. 937 above p. 345.
[947] Hoppe, 2011, p. 56.
[948] Mahoney (2000) fn. 939 above p. 213.

This Chapter argues that contract law and contracts could provide some solutions for the regulation of such risks and for the protection of the people involved (Section 22.4).

Finally, a coercion related argument against the validity of non-gratuitous contracts on human tissue is that such contracts should be always unlawful because one of the characteristics of the rules on privacy is the paradigm of non-commercialization of personal data, including the data contained in human tissue samples. Arguably, this assumption has its basis on Article 8 of the International Declaration on Human Genetic Data according to which "(p)rior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions."

One may argue that the aforementioned prohibition of inducing consent by means of financial or other personal gain is aimed at guaranteeing that consent is given freely. However, there are not compelling reasons to think that consent is not given freely in all cases in which financial or other types of personal gain are offered in exchange of the permission to collect, use or store human genetic data, human proteomic data or human biological samples. Moreover, as explained in Chapter 21.2 on consent, what counts for the protection of the person and her consent is the genuine exercise of substantive autonomy.

Furthermore, the most recent European legislation on data protection (e.g. the General Data Protection Regulation) does not include any rules precluding receiving financial or other types of personal gain for the collection, use or storage of genetic data. Considerandum 42 of the General Data Protection Regulation states that "(c)onsent should not be regarded as freely given if the data subject has no genuine or free choice or is unable to refuse or withdraw consent without detriment". This seems to confirm the idea that freedom of consent is paramount to the processing of data, but it does not necessarily entail its gratuity.

22.3.2 Commodification and human dignity

Generally speaking, the term commodification makes reference to permitting the purchase and sale of goods, which are deemed not to have a use value and not to be tradable on the market.[949] Commodification allows giving a use value and an exchange value to these goods.[950] According to some scholars, commodification involves two different processes: the first process transforms persons into

[949] Wancata, 2004, p. 204
[950] Ibid.

things, and the second one transforms human relations into contracts.[951] It has been also argued that commodification, in a broader sense, makes reference to the use of market rhetoric or "the practice of thinking about interactions as if they were transactions".[952]

In particular, when dealing with human body parts, it has been sustained that market language has pervasive effects and may be inadequate.[953] According to this understanding, the mere possibility of thinking of human tissue as an object of sale implies its commodification,[954] degrades the person and is contrary to human dignity.[955] In the words of Holland: "(c)ommodification contributes to a diminishing sense of personhood on an individual level, even as it erodes commitments to human flourishing at the societal level".[956] This degradation argument has also been constructed on the philosophical idea of incommensurability: since the market only provides for economic valuation, valuing human tissue only in economic terms degrades what has been valued.[957]

Those who oppose the sale of human tissue for the reason that it leads to the commodification of the human body and its parts, often forget that in practice a lawful market for human tissue already exists, whereby the only party excluded from obtaining any economic remuneration is the first transferor of the tissue. It is an uncontested fact that commercial enterprises (and sometimes also non-profit organizations) obtain tissue samples from medical institutions which in turn obtain them from donors.[958] The medical institutions and/or the commercial enterprises then transfer the samples for economic consideration, to patent entire cell lines or other bodily products or to develop commercial products that lead to extensive profit for these institutions or enterprises. Human tissue is already commodified, independently of whether or not the sale of human tissue by the first transferor is allowed. In this sense, insisting on using the language of "donation" or "gift" for the first transfer of human tissue hides the fact that considerable economic value is created in the subsequent transfers of the tissue.[959] Even if tissue is transferred as a donation, it becomes a commodity in the subsequent transfers because its use and possession have an economic value.[960] In the terms of Korobkin: "(i)t is only the providers of the necessary tissues, without which the research cannot be done, and new medical

[951] Marway (2014) fn. 934 above p. 582.
[952] Radin, 1987, p. 1859
[953] Nelking & Andrews, 1998, p. 30.
[954] Marway (2014) fn. 934 above p. 582.
[955] On the ways in which human dignity is used in debates about controversial biotechnologies see fn. 936 above.
[956] Holland, 2001, p. 263.
[957] Duxbury (1996) fn. 937 above p. 335
[958] Koepsell, 2009.
[959] Mahoney (2000) fn. 939 above p. 192. On the imbalance between donors and other users of human biological materials see Noiville, 2016, p. 146.
[960] Mahoney (2000) fn. 939 above p. 193.

treatments cannot be developed, who are singled out for remuneration prohibitions."[961] The question here, as formulated Muireann Quigley is: "if (...) we ought not to use the human vessel as a base commercial commodity, then should this prohibition not also extend to third parties? For those who are tempted to respond in the negative to this suggestion, there remains the challenge of adequately explaining why permitting income rights is wrongful commercialisation and commodification in one instance, but not in the other?"[962]

One may answer this question by insisting on the necessity of the de-commodification of human tissue, in which case a radical change in the way tissue is transferred and used would be necessary. Payments in the whole chain of transfers would have to be eliminated, as well as the rules for patents on bodily parts and bodily-derived products. However, as long as third parties are allowed to make profit from the use of human tissue, the question is not whether or not human tissue may be commodified, but whether to allocate to the first transferors of the tissue a share of the profits obtained from its use. Allowing first transferors to sell their human tissue would only imply a shift towards a system whereby market activity – and the fair allocation of the economic benefits – begins one step earlier and some kind of symmetry is established between the different parties of the chain of use of human tissue.

Furthermore, to admit that tissue has become a commodity does not necessarily lead to treating persons as commodities. From giving economic value to human tissue, it does not logically follows that the same value is given to the person.[963] The moral value of tissue does not equate to the moral value of the persons.[964] As a consequence, treating human tissue as a commodity does not necessarily entail a degrading effect. Firstly, because what is considered by some as degrading may not be seen by others in the same way. Assessments of what constitutes degradation are subjective and, as a consequence, contestable. Secondly, because transferors of human tissue may see their participation in the market as manifestation of self-respect and as a means to develop their own personal choices while considerably contributing to the benefit of other parties.[965] In the words of Duxbury: "(a)ctions which are accompanied by the consent of those who are party to them but which are considered by many to be degraded by commodification – so long as they advance the welfare of the relevant actors to a degree which outweighs any harmful effect which may be generated – ought not to be outlawed purely out of concern that commodification might lead to degradation."[966]

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[961] Korobkin, fn. 879 above p. 46.
[962] Quigley, 2014, p. 702.
[963] Resnik, 2002, p.142.
[964] Korobkin, fn. 879 above.
[965] Mahoney (2000) fn. 939above p. 205.
[966] Duxbury (1996) fn. 937 above 337.

For similar reasons, this book argues that the sale of human tissue (and its commodification) is not necessarily contrary to human dignity.[967]

Human dignity is perhaps one of the most controversial arguments against the transfer for profit of human tissue. The principle of human dignity has a double value: it is itself a guiding principle and a value to be protected, but it is also a criterion for the interpretation of other fundamental rights (e.g. health) and open norms of private law (e.g. public order and good morals).[968] However, the values that fill this unwritten principle of law are not determined. The determination of such values bear relevance not only for the assessment of whether or not the conclusion of a contract on human tissue is contrary to human dignity itself, but also for the assessment of whether or not such contracts are contrary to public policy, public order or good morals and therefore illicit.

Therefore, a question arises: What are the values that should fill the content of the principle of human dignity?

Even though no one questions the relevance of human dignity for the solution of bioethical and legal problems, the concrete manifestations of the principle of human dignity are less generally embraced. In the sphere of biolaw,[969] human dignity is an only apparently clear concept: it leads on occasions to completely opposite solutions for the same legal-ethical problem (e.g. the different human dignity based solutions to the beginning and end of life issues).[970] Human dignity is a widely acknowledged principle of law but the values that fill this principle are not always clear.

In general terms, two different tendencies in the understanding of human dignity can be identified. The first one focuses on the subjective dimension of human dignity and considers that its manifestation is a broad range of action of personal self-determination.[971] The second one focuses on the objective dimension of human dignity and sees human dignity as a limit to individual freedom with regards to the individual personal choices. According to this second view of human dignity, transactions on human tissue commodify the human body and therefore should be prohibited. These different (or even opposed) conceptions of human dignity have been also described as human dignity as empowerment and human dignity as constraint.[972] Furthermore, a different, third, understanding of human dignity has been proposed in academic literature: human dignity as social

[967] The content of the following paragraph draws partially on one of my published articles: Santamaria, 2017.
[968] Conti, 2014, p. 30.
[969] For a definition of biolaw see Chen, 2008, p. 56.
[970] Conti, 2014, p, 33.
[971] Casonato, 2006, p. 17.
[972] Beyleveld & Brownsword, 2002, p. 6. On a broader discussion on the concept of human dignity as a human value see: Feldman, 1999.

dignity.[973] According to the latter position, social dignity is conceived as the "right to a honourable life in terms of satisfactory material conditions".[974] The following pages of this subsection will outline firstly the main characteristics of these three conceptions of human dignity; secondly, the main critiques to these three conceptions; and thirdly, the assessment of whether human dignity in itself is a sufficient reason to prohibit non-gratuitous contracts on human tissue.

-*Human dignity as empowerment*

The conception of human dignity as empowerment derives the recognition of human rights from the intrinsic dignity of humans and attributes great importance to the protection of individual autonomy.[975] The understanding of human dignity as empowerment can be traced back to the first international declarations on human rights after the Second World War. The UN Universal Declaration of Human Rights[976] is a paradigmatic example of this understanding. Both the preamble[977] and Article 1[978] of this Declaration recognize the inherent dignity of all human beings. The ECHR does not explicitly mention the concept of human dignity. However, some scholars have derived from the reference to the Universal Declaration of Human Rights contained in the first considerandum of the Preamble to the ECHR[979] an indirect connection to the notion of human dignity.[980]

The conception of human dignity as empowerment is closely linked with the principle of autonomy: allowing the individual to make his/her own autonomous choices about his/her life protects human dignity.[981] Lord Millet in *Rees v Darlington memorial Hospital NHS Trust*[982] held that human dignity "(…)is increasingly being regarded as an important human right which should be protected by law."[983] In the same line of reasoning he argued in *McFarlane v*

[973] Marella, 2008; Marella, 2006.
[974] Marella, 2008, p. 126.
[975] The conception of human dignity as empowerment is defended for example by Patrick Capps: see Capps, 2009, p. 108. See also Post, 2000 at < http://escholarship.org/uc/item/8h98x8h9>.
[976] See fn. 23
[977] The relevant part of the preamble reads as following: "Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world (…)"
[978] Article 1 reads: "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood."
[979] The first considerandum of the Preamble reads: "(…) Considering the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10th December 1948 (…)" See fn. 24.
[980] Feldman, 1999, p. 689.
[981] The link between dignity and autonomy can already be found in Kant. See O'Connell, 2009, p. 273 with further reference.
[982] Rees v Darlington memorial Hospital NHS Trust [2003] UKHL 52.
[983] Ibid. Para 123.

Tayside Health[984] that "autonomy can be viewed as an aspect of human dignity and that the protection of autonomy can also be viewed as the protection of human dignity".

According to the conception of human dignity as empowerment, by reinforcing the scope and importance of freedom of contract, the principle of human dignity should underpin (rather than limit) freedom of contract. Since individual autonomy manifests itself in the exercise of contractual choice, and since there is a widely recognized line of thinking that links respect for human dignity with respect for individual autonomy, human dignity and freedom of contract form a virtuous circle: human dignity underpins the freedom to pursue the individual´s autonomous goals.[985]

The main critique to the conception of human dignity as empowerment is that it is an undetermined concept and may lead to different results in the adjudication of private disputes. In a hypothetical case where the human dignity (as empowerment) of two parties collides, it is uncertain which of the two should prevail.[986]

However, the uncertainty stemming from the use of human dignity as empowerment in private law relations does not necessarily entail negative consequences. The use of open norms or general clauses like public order, public policy or good morals in the adjudication of private disputes has also a variable character, depending of the outcome of the balancing of rights and interests involved. Similarly, the role of human dignity as empowerment can be derived from the role of other human rights in contract law. Adorno argued that in order for human dignity to be functional, it needs other notions that are usually presented using the terminology of rights.[987] In the same line, Beyleveld and Brownsword wrote that "the practical business of pressing one´s interests against others is conducted in terms of claimed human rights".[988]

-Human dignity as constraint

The conception of human dignity as constraint focuses on the existence of human duties, and particularly, the duty to not compromise one's own dignity.[989]

Under this conception, human dignity acts as a restraint of free choice.[990] Here human dignity is seen not only as something intrinsic and subjective to every

[984] McFarlane v Tayside Health, [1999] UKHL 50.
[985] Beyleveld and Brownsword, 2002, p. 207.
[986] Marella (2008), fn. 973 above p. 127.
[987] Andorno, 2009, p. 234.
[988] Beyleveld and Brownsword, 2002, p. 13.
[989] Beyleveld and Brownsword, 2002, p. 37: "The duty to not compromise one's own dignity is closely linked to the philosophical concept of "duties to oneself"." According to this concept, there is a duty not only to respect the dignity of others, but also one's dignity. On the concept of "duty to oneself" see Denis, 1997; Singer, 1959.

person, but also as the shared, objective, value that gives a community its particular identity.[991]

Explicit mentions of the need to protect human dignity, which support the conception of human dignity as constraint, are contained in the Oviedo Convention,[992] the CFREU,[993] and the Council of Europe's Recommendation on research on human biological materials.[994]

Beyleveld and Brownsword have suggested that human dignity as constraint is a new paradigm in modern bioethics and is "implicated in much recent thinking about the limits to be placed on biomedicine, reflecting the belief that biomedical practice in the twenty-first century should be driven, not by the vagaries of individual choice, but by a shared vision of human dignity that reached beyond individuals".[995] One may draw a parallel between this change of paradigm in European bioethics and a process that has been described by Marella as the juridification of human dignity in Europe:[996] human dignity has been used to limit the individual's own freedom.[997] According to Marella, this process can be clearly seen in cases where human dignity as empowerment and human dignity as constraint collide.

The conflict between these two conceptions has been exemplified in the (in)famous French dwarf-throwing case.[998] In this case, the *Conseil d'État* (the French administrative supreme court) declared that French municipalities have the power to prohibit shows that involve dwarf-throwing because of the need to protect public order (*ordre publique*) and human dignity. The *Conseil d'État* affirmed that human dignity is one of the components of the concept of public order and that the dwarf was compromising his own dignity by allowing to be

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[990] Beyleveld and Brownsword, 2002, p. 29.
[991] Hottois, 2000, p. 95.
[992] See for example the preamble and Article 1 of the Oviedo Convention. Moreover, the Explanatory Report accompanying the Oviedo Convention states in paragraph 9 that "(…) The concept of human dignity, which is also highlighted, constitutes the essential value to be upheld. It is at the basis of most of the values emphasised in the Convention." Similarly, paragraph 131 of the Explanatory Report states in relation to Article 21 that it "(…) applies the principle of human dignity set forth in the preamble and in Article 1."
[993] "Dignity" is the title of Chapter 1 of the Charter, and the principle of human dignity is laid down in its Article 1. Also Article 3(c) CFREU, containing the "prohibition on making the human body and its parts as such a source of financial gain", is embedded in the "Dignity" Chapter of the Charter.
[994] Article 1 of the Appendix of the Recommendation on research on human biological materials states: "Member States should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity, the right to respect for private life and other rights and fundamental freedoms with regard to any research activity governed by this recommendation."
[995] Beyleveld and Brownsword, 2002, p. 29
[996] Marella, 2008, p. 123.
[997] Marella, 2006, p. 272.
[998] Conseil d'Etat, Assemblée, du 27 Octobre 1995, 136727.

thrown as a projectile by putting himself in the situation of being treated as a mere thing.

As Marella convincingly demonstrated, two conflicting conceptions of human dignity are at stake in this case:[999] on the one hand, human dignity as constraint, restricting the dwarf to make his own choices and, on the other hand, human dignity as empowerment, in support of the dwarf's choice to put himself in a position that he considered the best for his own interests. A similar clash between the two conceptions of human dignity can be identified in the two German *peep show* cases.[1000] In these cases it was sustained that the woman's objectification constitutes an affront to human dignity.[1001]

The conception of human dignity as constraint has been vastly criticized.[1002] Firstly, scholars have submitted that this notion of human dignity comes into conflict with the individual's own sense of dignity and plays therefore a paternalistic and disciplinary role by restraining individual choices.[1003] Secondly, according to Marella, the notion of human dignity as constraint leaves to the judge the decision to determine whether individual human dignity has been violated.[1004] Finally, Marella also criticized the conception of human dignity as constraint because it may prevail over other desirable notions of human dignity such as social dignity.[1005]

-*Social Dignity*

Marella proposed to understand human dignity as social dignity.[1006] She maintained that social dignity is a "relational idea of dignity meant as the precondition for the individual's self-determination and personal development, as the cultural and political implications of one's self-reliance and self-respect, as the right to an acceptable standard of living and as a set of conditions likely to make a person a fully participant member of society".[1007] Accordingly, social dignity is closely linked to the notions of liberty and equality.

According to Marella, social dignity is firmly rooted in the European constitutional traditions and the relational dimensions of private law can be found in the social meaning of the human dignity clause. In her opinion, an understanding of Article 1 CFREU[1008] that takes into account the social

[999] Marella, 2008, p. 128.
[1000] *Bundesverwaltungsgericht* (BVerwG) 15 December 1981, *Neue Juristische Wochenschrift* 1982, BVerwG 30 January 1990, (1990) *Juristenzeitung*, 382.
[1001] Marella, 2008, p. 128.
[1002] See for example Jorion, 1999; Theròn, 1998; Levinet, 2003.
[1003] Marella 2008, p. 131 with further references.
[1004] Marella, 2006, p. 271.
[1005] Ibid.
[1006] Marella, 2008; Marella, 2006.
[1007] Marella, 2008.
[1008] Article 1 CFREU reads: "Human dignity is inviolable. It must be respected and protected."

understanding of human dignity may play a role in the constitutionalization of European private law.[1009] Marella considers that the other understandings of human dignity (i.e. human dignity as empowerment and as constraint) stem from an individualist liberal mode of legal reasoning[1010] and do not take into account the redistributive results that a contract might or not produce.[1011]

This book submits that if Marella's idea of social dignity is taken as a base for assessing the (in)validity of contracts on human biological samples, it is necessary to consider the distributive outcomes of the particular contract in order to determine if in the concrete case the dignity of the individual has been violated. If a contractual agreement, from a distributive viewpoint, has a negative impact on the social conditions of the individual, the agreement is to be considered contrary to social dignity. In this case, the relevant legal rules on the validity of contractual agreements should be interpreted and applied in the light of human dignity (understood as social dignity) in order to deny the validity of the agreement.

However, it also has to be considered that human dignity (be it understood as social dignity or otherwise) is not the only relevant fundamental right or policy consideration in a contract case. Even in the cases when a contract is not contrary to the social dignity of the individual, the contract can be deemed invalid on other grounds. As Colombi Ciacchi pointed out, court and administrative decisions are not market-neutral.[1012] A decision allowing non-gratuitous contracts on human tissue because it enhances the social wellbeing of the transferor of the tissue could foster the expansion of a market that might not be desirable for other kind of policy or moral considerations.

-Pluralism and human dignity

Beyond the division between those who consider that human dignity has a subjective dimension (human dignity as empowerment), those who argue in favour of its objective dimension (human dignity as constraint), and those who argue for its social dimension (human dignity as social dignity), the notion of dignity represents at the same time at least three different but compatible ideas: dignity as an intrinsic universal value (that precludes an attack to the freedom, identity or integrity of the person), dignity as self-determination (as a means for a moral agent to decide about certain ethically relevant choices) and dignity as a social value.[1013]

[1009] Marella 2008, p. 131.
[1010] Ibid. p. 130.
[1011] Marella, 2006, p. 274.
[1012] Colombi Ciacchi, 2008, p. 159.
[1013] Conti, 2014, p. 30.

This book is deeply committed to the ideas of autonomy and value pluralism (see 22.2.1) and does not deny the understanding of human dignity as a social virtue or expression of a core of values prohibiting public or private actors' unjustifiable infringements in a person's freedom, identity or integrity. However, this book adheres to the view according to which the answer to the question of what values should fill the principle of human dignity is not a universal one, but varies from person to person. In a pluralistic legal system, a regulatory definition of human dignity is inadmissible because that legal system would cease to be pluralist and would become a legal system that determines once and for all which vision of the world and of the self should be followed.

In a pluralistic society, different philosophical and moral views and solutions for different bioethical problems coexist. Therefore, it is not possible to find solutions to bioethical problems by using a common and universal moral. Notions of ethical and legal relevance like human dignity, as has been shown, are susceptible of different and even opposed readings.[1014]

For these reasons, the individual's personal understanding of her own human dignity finds in the principle of pluralism a confirmation of the validity of her own subjective understanding.[1015] It is therefore necessary to accept that every person has her own ethical ideas and choices, and that the practical implementation of these choices should be encouraged.[1016] The only limit to one's choices is the obligation to not cause harm to others.

If one wants to embrace a pluralistic and liberal vision of society and its legal system, one would have to admit that human dignity cannot be considered per se an argument against non-gratuitous contracts on human tissue for research and commercial uses thereof. It is up to the person to decide, according to her own human dignity understanding, whether or not engaging in these kinds of transactions is detrimental to herself. As a consequence, a non-gratuitous contract should not be deemed contrary to the first transferor's human dignity, if she has manifested her informed consent and has freely[1017] agreed with the contractual terms.

22.3.3. Altruism and solidarity

The supporters of the prohibition of non-gratuitous contracts on human tissue maintain that, if permitted, such contracts would crowd out altruism behaviour

[1014] D'Avack, 2009, p. 13.
[1015] Casonato, 2005, p. 26.
[1016] D'Avack, 2009, p. 13.
[1017] "Freely" here does not refer to the mere formal freedom of contract but to substantive party autonomy. On this see Colombi Ciacchi, 2010, p. 3.

in the transfers of human tissue.[1018] This argument is based on two different assumptions. The first assumption is that individuals would not act altruistically if given the opportunity to give for profit their human tissue. The second assumption is that altruistic behaviour is superior to self-interest from a moral point of view.

Regarding the first assumption, it is uncertain that permitting payments in exchange of human tissue would discourage individuals to engage in altruistic behaviour and transfer their tissue for free.[1019] However, if one assumes that altruism in human tissue transfers would disappear once sales of tissue are allowed, then, logically, altruism would only exist when there is no other option available. Altruisms, in this hypothetical scenario, would be forced altruism. When altruism is presented as the only option available, it is not real altruism.[1020] One may also argue that individuals may be willing to transfer their human tissue for the purposes of benefiting scientific research, but would not be willing to transfer it for free given the fact that all the other actors in the chain of use of human tissue profit from it economically.[1021] In fact, patents on genes and cell lines are constantly granted to researchers and companies.[1022] By 2017 the global biotechnology market is estimated to be worth 414.5 billion dollars.[1023] Companies often make use of non-gratuitous material transfer agreements (MTAs)[1024] for the exchange of tissue and other human biological samples to be used in research with commercial purposes. Whilst the argument of altruism and solidarity is strong when considering the use of human body parts for therapeutic purposes, one might claim that the same argument does not hold the same strength when it comes to the use of human tissue for commercial purposes. It would seem as if two different standards apply to the different parties involved. On the one hand, the first transferor is prohibited from obtaining any financial gain from the use of her tissue. In this case the standard

[1018] On the necessity of altruistic behaviour in the transfer blood see the seminal work of Titmmus, 1970. Although Timmus limits his analysis to the transfer of blood, his idea that altruistic and voluntary donation of blood is morally and socially superior to a payments system has permeated the debate over the transfer of other human body parts. For an analysis of Timmus' arguments see Sýkora, 2016.
[1019] Mahoney (2000) fn. 939 above.
[1020] Because the original transferor of the tissue would be the only one engaging in altruism behaviour, Dickinson sustained that one-way altruism is better called exploitation. See Dickenson, 2004, p. 113.
[1021] Nils Hoppe proposed a three-tiered model whereby the sale of human tissue should only be permitted for the purposes of commercial research. When the aim of the transfer of tissue is to improve the health of third parties, altruism should be the rule, and when the aim is saving another person's life, public interest should override individual rights. See Hoppe, 2016.
[1022] On gene patents see Koepsell, 2009.
[1023] Global Biotechnology Market by Application (Biopharmacy, Bioservices, Bioagri, Bioindustrial), by Technology (Fermentation, Tissue Regeneration, PCR, Nanobiotechnology, DNA Sequencing & Others) - Industry Analysis, Size, Share, Growth, Trends and Forecast, 2010 - 2017 Report at <http://www.transparencymarketresearch.com/biotechnology-market.html>
[1024] For the notion of Material Transfer Agreement see: Rodriguez, 2005, p. 23.

of altruism and solidarity applies. On the other hand, companies are entitled to conclude non-gratuitous contracts (e.g. MTAs) on the tissue that they previously obtained for free and to obtain patents on human genes. In this case the standard of altruism and solidarity does not apply.

Regarding the second consideration, although altruism should be encouraged, in a pluralistic society, the competing value of self-interest should not be excluded from the range of individual choice on the grounds of the alleged moral superiority of altruism. There is nothing inherently wrong in someone willing to sell her tissue for selfish reasons.[1025] Self-interest and altruism are both equally valuable, from a perspective that takes autonomy and pluralism seriously, independently of the personal preferences one may have. In the words of Mahoney: "(…) if sources actually prefer to be paid, why should legal rules and social norms act to foreclose their preferred options".[1026] If contracts for profit on human tissue were allowed, individuals would have a choice between transferring their tissue on genuine altruistic basis or for their own personal benefit.

If altruism is to be encouraged, as I believe, one could imagine more creative and less intrusive ways of promoting it. Contract law and contracts could play a role in this promotion (Section 22.4).

22.4 Governance, autonomy and paternalism in non-gratuitous contracts on human tissue

In order to protect the rights and interests of the sellers of human tissue, at least two different mechanisms could be jointly put in place. An already existing mechanism, in the form of procedural paternalism, is the existence of research ethics committees that are involved in the approval of genetic research projects by assessing whether or not a project for research on human tissue complies with the necessary ethical standards. The second mechanism could be derived by contract law, in general, and contracts in particular, as mechanisms of governance and self-governance respectively.

The concept of governance[1027] comprehends different meanings depending on the academic discipline that uses this concept.[1028] However, some scholars have attempted to give a general definition of governance that fits all disciplines and

[1025] Hoppe (2011) fn. 947 above p. 60.
[1026] Mahoney (2000) fn. 939 above p. 217.
[1027] For scholarly literature on governance see: Levi-Faur, 2010; Williamson, 1998, p. 75-79.
[1028] For a brief overview of the governance definitions and discourses see: Colombi Ciacchi, 2014, p. 120-134 with further references.

all kind of governance.[1029] This section relies on the concept of contract governance[1030] given by Möslein and Riesenhuber.[1031]

Möslein and Riesenhuber have distinguished four different topics of contract governance:[1032] 1) Governance of contract law; 2) Governance of contracts; 3) Governance by means of contract law; and 4) Governance through contract.

1) Governance of contract law refers to the study of the institutional framework whereby the rules for contracts are set.[1033] This institutional framework is the result of the interplay between national and supranational legislators, but also advocacy groups and academic experts.[1034]

2) Governance of contracts refers to the analysis of contract law rules laid down by the actors within the abovementioned institutional framework. The aim of this topic is to create and facilitate the grounds for the realization of the autonomous goals of the parties via contractual co-operation. Möslein and Riesenhuber identify market economy and freedom of contract as the main elements of the framework on which the governance of contracts operates. Freedom of contract entails the freedom to choose the contractual partner and determine the contractual content. However, also public policy considerations are part of the framework of the governance of contracts.[1035] According to Möslein and Riesenhuber, "if we look at the purpose of allowing the parties to pursue and realise their own aims, the difficulty in structuring the framework is to find the proper balance between excessive protection (and regulation) with its infringement of individual freedom, on the one hand, and undersized protection, on the other".[1036]

3) Governance by means of contract law refers to the study of the use of contract law as an instrument of the State to pursue goals that are extraneous to the ones of the contractual parties.[1037] Möslein and Riesenhuber argue that when contract law is used to achieve such extraneous goals, there seems to be an imminent danger of intrusion into private autonomy and freedom of contract. However, governance by means of contract law may also be an instrument of deregulation:[1038] "From a viewpoint of governance, we thus consider the withdrawal of more rigid forms of state influence and control in favour of a

[1029] See for example, Issalys, 2005, cited in Colombi Ciacchi, 2014, p. 123.
[1030] On literature on contract governance see: Williamson, 1979, p. 233-26; Williamson, 2002, p. 438-443.
[1031] See fn. 881
[1032] Möslein & Riesenhuber, 2009, p. 12.
[1033] Ibid.
[1034] Ibid, with further references.
[1035] Ibid. p. 23.
[1036] Ibid.
[1037] Ibid. p. 25.
[1038] Ibid, p. 26.

regulation with the means of contract law".[1039] A possible way for the legislator to influence private behaviour is for example to offer a set of choices or options.[1040]

4) Governance through contract refers to the situation where the contract itself provides a framework for the (self-)regulation of the relationship between the contractual parties. According to Möslein and Riesenhuber, governance through contract is of particular relevance in cases where the contractual relationship is similar to an organisational structure, e.g. multiparty contracts and networks.[1041] Furthermore, "self-commitment by means of governance through contract has the potential to go beyond the individual contract or the relationship of the parties (…) where parties make a promise for the benefit of third parties".[1042]

According to Möslein and Riesenhuber, these four topics may overlap and/or complement each other. This book relies on this categorization of contract governance to analyse the role that non-gratuitous contracts –as a means of self-regulation– may play for the protection of the rights of the first transferor of human tissue for profit.

For this purpose, the following pages will describe and compare three different cases of self-regulation of the use of human tissue, including one evident case of governance through non-gratuitous contracts.

22.4.1 First case: Washington University vs William J. Catalona

In 2007 the United States Court of Appeals decided on the case *Washington University vs William J. Catalona*[1043] involving a contract on human biological samples:

From 1983 until 2003, a physician and researcher employed by the University of Washington (UW), Dr. William J. Catalona, collected human biological samples such as blood and tissue removed during surgeries for the subsequent use in research for prostate cancer. Following his example, many of his colleagues did the same. As a general rule, the University of Washington provided most of the funding to operate and maintain the biorepository. For the purposes of genetic research on cancer Dr. Catalona and other physicians had invited many individuals to participate by donating prostatic tissue and blood samples. The informed consent forms that participants signed used the term "donation" for describing the transfer of the human biological material from the patient to the

[1039] Ibid. p. 27.
[1040] Ibid, p. 26.
[1041] Ibid, p. 32.
[1042] Ibid, p. 33.
[1043] Washington University v. William J. Catalona, M.D. No. 06-2286. United States Court of Appeals for the Eight Circuit. June 20, 2007. For literature on this case see Rao, 2007, p. 374.

physician employed by the UW. These consent forms stated: "(…) biological samples may be used for research with our collaborators at (UW), other institutions, or companies". Moreover, the consent forms typically provided that "by participating in the study, the RP (Research Participant) "agree(s) to waive any claim (he) might have to the body tissues that (he) donate (s)" and also "waive(s) the right to any new material or process developed through research involving (his) tissues." RPs also were informed by the consent forms: "Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time." Some consent forms indicated that RPs could "request destruction of their biological materials if they changed their minds about participating in the study."

RPs had to read as well a document with information about the genetic research. The document contained, as the informed consent form, the term "donation" to describe the person's participation in the research. In addition, the document warned the patients of the impossibility of claiming any economic benefit for the donation or any of the medical or scientific products developed as a consequence of the research on their tissue.

During several years other academic institutions received biological samples from the biorepository in order to carry on researches in prostate cancer with the collaboration of the UW or independently. Dr. Catalona transferred materials from the biorepository to other institution using the so called "Material Transfer Agreements" (MTA). The MTA's were signed, as a general rule, by an authorized officer of the UW and a researcher. Several of the agreements signed personally by Dr. Catalona recognized the UW as the owner of the samples.

In 2003, Dr. Catalona accepted a position in the Northwestern University of Chicago and given the fact that he wanted to continue with the genetic research on prostate cancer with the samples he had collected during his period in the UW, he sent a letter to the patients that had donated biological samples. The letter informed the patients about his departure of the UW and asked them to transfer to him the biological material. The directors of the WU never approved the aforementioned document.

Furthermore, Dr. Catalona massively asked the patients to sign and hand back the following form: "I have donated a tissue and/or blood sample for Dr. William J. Catalona's research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to Dr. Catalona to be used only at his direction and with his express consent for research projects." Almost 6000 participants signed the form.

The University of Washington filed an action seeking a judgement declaring his property rights on the human biological samples and enjoining Dr. Catalona from interfering with the University biorepository. The claim was successful in both

the Court and the Court of Appeals, and the ownership right of the samples was denied to Dr. Catalona.

The United States District Court of Appeals allowed Washington University's claim on the basis of the following arguments:

Since the three constitutive elements of a gift under Missoury law (donative intent, delivery and acceptance) were met, the research participants' made a donation to the University. The requirement of delivery was met when the research participants provided the samples at the moment of the donation. The requirement of donative intent was met because the forms signed by the donors manifestly specified that the contract was a donation of tissue and/or blood. In relation to the third element (acceptance), the defendant, Dr. Catalona, argued that this requirement was not met since the research participants retained some rights on their samples and as a consequence, the transfer of property could not be completed in absolute terms. The Court rejected this argument and held that the rights retained by the research participants on their samples were expressly limited to the option to discontinue participation in the study, to avoid answering additional questions, donating more biological materials, or allowing their biological materials to be used for further research: such rights could not be equated with or interpreted to include broad privileges or proprietary interests. Moreover, the Court argued that during the research process on prostatic tissue or blood, the samples can be entirely consumed and therefore the donor will not maintain any property interest. For the aforementioned considerations, the Court declared that the University of Washington was the owner of the samples and denied to Dr. Catalona any kind of rights or faculties on them.

In this case the use of human tissue is governed by the consent form that the research participants signed. The first transferors of the tissue (i.e. the research participants) had only limited rights in relation to their tissue and the research: firstly they were not entitled to any claims on their tissue except for the destruction or for the withdraw from participating in the study and secondly, they could not claim any economic benefit from the donation of the tissue or from any product developed by making use of the samples.

22.4.2 Second case: Greenberg vs Miami Children's Hospital

In 2003, the United States district court decided a case (*Greenberg vs Miami Children's Hospital*[1044]) involving the distribution of economic benefits stemming from genetic research carried on human tissue:

[1044] Greenberg v. Miami Children's Hospital Research Institute. United States District Court, S.D. Florida, Miami Division. May 29, 2003. 264 F.Supp.2d 1064.

By the year 1987 it was still impossible to discover who was a carrier of the Canavan disease and there were no prenatal tests to determine if the foetus had it. Canavan disease is a genetically inherited incurable degenerative disorder that causes childhood death and is most common among Ashkenazi Jews. One of the plaintiffs, Mr. Greenberg, contacted Dr. Matalon, a medical researcher associated at that time to the University of Illinois, and asked him for help to carry out genetic research on the disease. In particular, Mr. Greenberg asked Dr. Matalon to help discovering the genes that caused this disease in order to be able to create tests to identify the carriers.

At the beginning of the research, Mr. Greenberg and another plaintiff (a private non-profit organization: *National Tay-Sachs and Allied Diseases Association,* NTSAD) localized families with the Canavan disease and convinced them to donate tissue samples, blood and urine, and to financially contribute to the research. Mr. Greenberg and NTSAD also created a confidential data base with the epidemiological and medical information of other families with the disease. In 1990, Dr. Matalon stopped working at the University of Illinois and started working at the Miami Children's hospital. However, the agreement between the plaintiffs and Dr. Matalon persisted and he continued to accept blood samples and economic support.

The plaintiffs argued that it was their "understanding that any carrier and prenatal testing developed in connection with the research for which they were providing essential support would be provided on an affordable and accessible basis, and that Matalon's research would remain in the public domain to promote the discovery of more effective prevention techniques and treatments and, eventually, to effectuate a cure for Canavan disease."[1045]

In 1993, Dr. Matalon and his team successfully isolated the gene responsible of causing Canavan disease. The plaintiffs argue that after the discovery they continued to provide more samples of tissue and blood.

In 1994, without the knowledge of the plaintiffs, Dr. Matalon applied for a patent on the genetic sequence that was discovered. The patent was granted in 1997, which allowed him to restrict any activities related to the Canavan disease gene, including portability testing, pre-natal testing, gene therapy, and any other treatment, as well as research on the gene and its mutations.

The plaintiffs maintained that they did not know about the existence of the patent until 1998, when the Miami Children's Hospital and Dr. Matalon started selling licenses to perform testing and research, limiting in that way public access to any information. Some of the concerns of the plaintiffs were that the

[1045] Ibid. p. 3.

fees for testing and access to information would make it difficult for other researchers to carry out new studies and for people to get the diagnostic testing.

The plaintiffs sued Dr. Matalon and Miami Children's Hospital on different grounds. All claims except the one of unjust enrichment were dismissed by the court.[1046]

For the analysis of the unjust enrichment claim the court maintained that "(u)*nder Florida law, the elements of a claim for unjust enrichment are (1) the plaintiff conferred a benefit on the defendant, who had knowledge of the benefit; (2) the defendant voluntarily accepted and retained the benefit; and (3) under the circumstances it would be inequitable for the defendant to retain the benefit without paying for it* (…)" and that "(c)*omplaint has alleged more than just a donor-donee relationship for the purposes of an unjust enrichment claim. Rather, the facts paint a picture of a continuing research collaboration that involved Plaintiffs also investing time and significant resources in the race to isolate the Canavan gene. Therefore, given the facts as alleged, the Court finds that Plaintiffs have sufficiently pled the requisite elements of an unjust enrichment claim and the motion to dismiss for failure to state a claim is DENIED as to this count.*"[1047]

The *Greenberg v. Miami Children's Hospital* case led to a debate on the convenience of concluding contracts (instead of, for example, simpler informed consent forms) to regulate the use of human tissue for genetic research and commercial application thereof in the biotechnology field. Some scholars maintain that if contract terms are used, the protection of the rights of the persons involved would increase and it would be possible to monitor more effectively the opportunistic behaviour of the recipients of the tissue samples.[1048] Furthermore, as Anna Nichols Hill has convincingly argued, even though informed consent is an important tool for the protection of the transferors of the samples, it is not sufficient for the purposes of allocating the benefits of successful genetic research.[1049]

22.4.3 Third case: PXE International

The case *PXE International* did not reach the courts but has been object of debate among legal scholars and bioethicists:[1050]

In 1995 Ms. Terry and her husband found out that their two children were affected by pseudoxanthoma elasticum (PXE), a rare genetic disease that causes

[1046] The other claims were: lack of informed consent, breach of fiduciary duty, fraudulent concealment, conversion, and misappropriation of trade secrets.
[1047] Greenberg v. Miami Children's Hospital Research Institute, p. 12.
[1048] Bellivier & Noiville, 2004; Dick, 2002; Weck, 2005, p. 1057.
[1049] Nichols Hill, 2002, p. 270.
[1050] See generally www.pxe.org. For scholarly literature on this case see: Smaglik, 2000; Nichols Hill, 2002; Rao, 2007.

the calcification of the skin, eyes and arteries' elastic tissue. It became clear for them that the researchers with whom they shared blood for the purposes of finding a cure were not willing to share it with other scientists. Moreover, the scientists studying the blood samples were able to contact only a reduced number of families affected by the same disease, and therefore, a fast significant progress was not expected to be achieved, as it would be if more research participants would be involved in the research.

The Terry family decided then to create a patient advocacy group: PXE International. In the course of four years they managed to locate around 2000 people with PXE disease, to set up a large biorepository with blood and tissue samples from those patients, and began raising money for the research. The idea behind PXE International was to maintain control over research on the samples by exchanging them with researchers for a valuable consideration. Given the fact that PXE International managed to procure a vast number of samples and funding, many researchers were eager to make use of the organization collection on the group terms. The contract between researchers and PXE International stated that the latter was entitled to any ownership rights on patents derived from the research. This condition allowed the organization to share among their members any profits arising from the discoveries, and to ensure the affordability of genetic tests.

PXE International provided samples of blood and tissue from patients with PXE disease to scientists of the University of Hawaii. In February 2000, Charles Boyd, a University of Hawaii pathologist, isolated the gene associated with PXE. Even though Dr. Boyd signed the standard PXE International contract, and named Ms. Terry as part of the research team on the patent application, his contract with the University of Hawaii granted the university the rights on his inventions.

PXE international and the University of Hawaii reached an agreement on 2001, where PXE International maintained the right to take the licensing decisions, and the profit deriving from marketable products were to be split between both parties. The patent was granted in 2004 to PXE International.

22.4.4 Comparing the three cases: differences and similarities

The three cases described above differ in the degree of participation of the first transferors of the tissue samples, in the kind of agreements and the conditions set for the use of the samples in the research, and in the level of protection of the original transferor's rights.

In *Washington University vs. William J. Catalona* and in *Greenberg vs Miami Children's Hospital* the first transferors had only limited rights in relation to their samples. In the former case, the consent form that the research participants signed governed the use of human biological samples for genetic research. In the

latter case, this use was governed by the agreement for collaboration between the parties. Both cases have in common that the original transferors of the samples did not agree on any kind of apportionment of the benefits that could result from the research on their samples. In *Washington University vs William J. Catalona* the research participants could not claim any economic benefit from the donation of the samples or from any product developed by making use of the samples. In *Greenberg vs Miami Children's Hospital,* the plaintiffs had to resort on a claim for unjust enrichment in order to get a part of the economic benefits resulting from the research.

In the PXE International case, the relationship between the parties was governed by a contract that clearly allocated rights and duties in both parties. The PXE case has been described as a collaborative model for genetic research and for the allocation of the benefits stemming from this research.[1051] Unlike in the previous two cases described in this section, in the PXE case a non-gratuitous contract was concluded between a non-profit advocacy group (PXE International) and the researchers. Under the contract, the profits resulting from the research were to be shared between the researchers and PXE international. This condition allowed PXE to share the profits among its members (the first transferors of human tissue) and to ensure the affordability of genetic tests to them. In this way, the interests of the transferors of the samples were protected.

One may describe this case as a perfect example of governance through contract. Indeed, the contract provided a framework for the self-regulation of the relationship between the contractual parties, i.e. PXE and Dr. Boyd. Moreover, the contract had an indirect impact on third parties, i.e. the original transferors of the samples, by allowing PXE to share profits among its members and to ensure the availability of genetic tests that would otherwise be protected via patent rights.

Preliminary conclusions

The analysis of the three aforementioned cases shows how the possibility of concluding non-gratuitous contracts on human tissue for research is desirable from a theoretical and from a practical perspective. From a theoretical perspective, it allows for the expansion of the sphere of personal freedom and autonomy. In a liberal society, the legislator should refrain, inasmuch as possible, from prohibiting a priori behaviours that fall within the realm of individual autonomy. On the contrary, the State should grant the appropriate conditions for the implementation and development of personal choices.

[1051] Hill, 2002, p. 278.

From a practical perspective, contract law and contracts constitute the instruments for the implementation, development, and protection of the person and her personal choices. If the sale of human tissue and other gratuitous and non-gratuitous contracts on human tissue were allowed, the transferor (seller) could not only be granted statutory protection (e.g. data protection laws, informed consent laws) but also all the contractual protection stemming from contract law or from the contract itself.

Legal scholars have already identified some advantages that a contractual model could have over other models (proprietary or informed consent models) for the use of human tissue for research.[1052] A contractual model may contribute to the rebalancing of the relationship between the first transferor and the transferees; it could help organizing the circulation of human biological samples[1053] and it may prevent researchers' conflict of interests.[1054]

In addition to these advantages, a stronger protection to the rights and interests of the first transferor of human tissue could be derived from the interaction of contractual mandatory norms and default rules. Contractual mandatory norms could impose strong pre-contractual and contractual informational duties on the researchers.[1055] These duties could include information on the nature of the research, on whether or not financial gain is expected to be derived from it, on the different uses that will be given to the tissue, and the possibility of transferring the tissue to other parties.[1056] Based on this information, the first transferor of tissue could decide, for example, whether or not she wants to transfer the tissue in exchange of economic remuneration. Default rules could constitute the basis of different contractual models for the transfer of human tissue. One could imagine default rules on gratuitous transfers when the purpose of the research is not commercial, but for example, strictly academic.

The most evident practical benefit of allowing non-gratuitous contracts on human tissue is the possibility for the first transferor of obtaining a direct economic benefit from the transfer of tissue. One could imagine different types of contracts for the transfer of the tissue in exchange of an economic remuneration:

The contract of sale comes first to mind, but other contracts, as a non-gratuitous lease of use, could be perfectly suitable for the regulation of the use of human tissue, in addition, of course, to all the atypical contracts imagined by the parties (e.g. PXE International) for the distribution of the benefits arising from the research. One can also imagine contracts whereby obtaining an economic

[1052] Noiville, 2016, p. 145.
[1053] Ibid. 147.
[1054] Ibid. 148.
[1055] Pre-contractual and contractual informational duties are consistent with a liberal, autonomy based theory of contract law. On this see Gutmann, 2013, p. 12.
[1056] These duties would be consistent with the informational variation of "nudging" paternalism.

remuneration for the transfer of the tissue is conditioned to the positive outcome of the research or to the amount of the actual economic profit obtained from the findings of the research.

Depending on the type of contract, the parties could attach conditions (precedent and subsequent), terms and limits to the use of tissue. Furthermore, depending on the law of the country, different contractual remedies could be available in case of breach of the contract. Illegality and public policy could constitute the grounds for the nullity of a contract in the cases where, for example, the research project does not meet the necessary ethical requirements. Furthermore, contractual categories like duress, mistake and fraud, could be used to invoke the nullity, annullability or unenforceability of the contract when the consent of one of the parties is lacking or vitiated.

Moreover, the parties of the contract could agree, among other things, on the period of use of the tissue, the limitations for transferring the tissue samples to third parties, the types of research that can be carried out on the tissue (commercial, academic, for a specific disease, for several diseases, etc.) and the procedures to follow in case of unexpected findings.

Finally, contracts (non-gratuitous and gratuitous) on human tissue have the advantage that they do not ignore the requirements of informed consent. On the contrary, if these types of contracts were allowed, informed consent would constitute a fundamental element for the formation and validity of such contracts.

22.5 Concluding remarks, recommendations and suggestions for legislative reform.

This Chapter analysed three arguments against the validity of non-gratuitous contracts on human tissue: the argument according to which these contracts are tainted by economic coercion and lead to the exploitation of the poor; the argument according to which non-gratuitous contracts commodify the person and are contrary to human dignity; and the argument according to which the conclusion of this type of contracts casts out the principles of altruism and solidarity.

Drawing on Raz's conception of autonomy and Fateh-Moghadam and Gutmann's analysis of paternalism, this Chapter has demonstrated how all the three aforementioned arguments are, to a certain degree, paternalistic. The analysis of each of these arguments has also shown that they do not sufficiently justify imposing a prohibition on the conclusion of such contracts. Instead of such a ban, less intrusive forms of protecting the autonomy of the first transferor of human tissue –while at the same time respecting value-pluralism– could be derived from contract law, in general, and contract drafting, in particular. The analysis of

three different cases involving acts and contracts on human tissue has also shown how the conclusion of non-gratuitous contracts on human tissue can work as a mechanism of governance through contract (e.g. PXE) that is desirable from a practical and a theoretical perspective. From a theoretical perspective, allowing such contracts would expand the available range of valid individual choices in a manner that is consistent with the conceptions of autonomy and value pluralism endorsed by this book. From a practical perspective the advantages are numerous: the first transferor of tissue would enjoy at the same time the protection provided by all statutory and contractual provisions; the relation between the first transferor and the transferees could be rebalanced via contractual mechanisms; the interaction between mandatory norms and default rules could achieve a strengthened protection of the person's autonomy; the first transferor could obtain a direct economic benefit from the transfer of the tissue; the parties could agree on different contractual clauses and conditions for the use of tissue in research and finally, the conclusion of non-gratuitous contracts would be consistent with the requirement of informed consent.

On the basis of the aforementioned conclusions this book proposes the following recommendations and suggestions for legislative reform:

1) It is desirable to regulate, via contract law legislative provisions, the tissue transfers of human tissue for the purposes of research.
2) This regulation should allow the conclusion of sales and other non-gratuitous contracts on human tissue between first transferor and the first recipient. Following this recommendation would entail the elimination of the prohibition of financial gain contained in Article 3 CFREU and Article 21 of the Oviedo Convention.
3) Regarding contracts between the first transferor and the first recipient, this regulation should place on the first recipient, prior the conclusion of the contract, a clear set of information duties towards the first transferor of the tissue. Such information duties should include, in addition to the ones described in the recommendations of section 21.4, the following: information on whether or not financial gain is expected to be derived from the research on the tissue sample and the possibility of transferring the tissue to other parties.
4) At least the following items should also be included as mandatory contractual clauses for the transfer of tissue between the first transferor and the first recipient: a) the number and quality of the samples that will be obtained; b) the intended use and disposal of the sample during and after the research; c) the intended duration of the use and storage of the obtained data; d) the confidentiality of the information and who will be able to access that information; e) the potential commercial use of the sample and the data; f) whether or not financial gain is expected to be

derived from the research on the tissue sample and; g) the possibility of transferring the tissue to other parties

5) The proposed contract law regulation should include mandatory and default rules for contracts between the first transferor and first recipient.
6) In addition to the default and mandatory rules proposed in section 21.4, this book proposes a default rule prescribing the gratuitous transfers of tissue for all types of contracts when the purpose of the research is not commercial, but for example, strictly academic.
7) Regarding contracts between the first recipient and subsequent recipients, mandatory rules should require that, when technically possible, the first recipient should warrant that valid consent has been obtained according to all applicable laws.
8) Regarding contracts between the first recipient and subsequent recipients, mandatory rules should require that such contracts must conform to the limits set in the original consent of the first tissue transferor.

Part 7

CONCLUSIONS

23

Chapter 23

SUMMARY OF CONCLUSIONS

PART 7 CONCLUSIONS

CHAPTER 23 Summary of conclusions

The aim of this book was to determine, from a comparative perspective, the limits to the validity of contracts on human tissue in Italy and England. The following sections provide a summary of the conclusions for each of the different Parts of this study.

23.1 On the limits stemming from international and supranational law sources

23.3.1 On the limits stemming from fundamental and human rights documents

There is no case law on the Italian or EU level that leads to the direct horizontal application of a supranational norm in matters related to acts of disposition of the human body.

Only in rare occasions have Italian courts granted horizontal effect to other sources different than the Constitution. As a consequence, it does not seem likely that Italian courts will directly apply a supranational norm on human dignity or fundamental rights to enforce a limit to the validity of a contract on human tissue.

In England it seems unlikely that judges will grant horizontal effect to supranational legal documents on fundamental rights other than the ECHR, as incorporated in the HRA 1998. In some cases human rights documents have not been incorporated into national law at all (e.g. UDHR), and in some other cases, the UK has decided to opt-out from them (e.g. CFREU). However, because English courts have to take into account the case law of the ECtHR when solving a case where a ECHR right is involved, supranational legal documents like the Oviedo Convention still hold an interpretative value in solving human rights cases between private parties.

For these reasons, one may argue that in Italy, the relevant norms of the UDHR, ECHR, the Oviedo Convention and the CFREU constitute limits to the validity of contracts on human tissue. In England, arguably only the relevant provisions of the HRA 1998 and the Oviedo Convention have an effect for the interpretation or determination of the validity of such contracts.

23.1.2 On the limits stemming from the GDPR

The GDPR may impose direct and indirect limits to the validity of contracts on human biological samples. A contract on human biological samples that involves the processing of personal data is bound to the principles of the GDPR: lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation and integrity and confidentiality. These principles do not apply to anonymous information. Pseudonymised data are not excluded from the application of the GDPR principles.

Particularly relevant for the determination of these limits is the purpose limitation principle (Article 5(1)b GDPR). It prescribes that further processing of data for archiving purposes in the public interest, or scientific purposes shall, in accordance with the safeguards included in Article 89(1) (e.g. pseudonymisation measures), not be considered to be incompatible with the initial purposes to which the data were originally collected.

Furthermore, with certain exceptions, the GDPR prohibits the processing of special categories of personal data, including genetic and health data. The exceptions to this prohibition include the cases when explicit consent of the data subject is given to the processing of genetic data for one or more purposes, and the cases in which processing is necessary for scientific research purposes or statistical purposes. Arguably, a contract involving the processing of genetic or health data that does not fall within one of the exceptions of Article 9.2 GDPR may be declared invalid because of its contrariety to mandatory law.

Article 7 GDPR prescribes the conditions for consent for the processing of personal data. Among other conditions, according to Article 7.2, if the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters. Therefore, the question arises whether a requirement for the validity of a contract for the removal and use of a human biological sample in research should consist in asking for two separate types of consent: one consent for the removal of the sample and one for the processing of the data associated to the sample. Moreover, one could argue that a contract that does not allow for the withdrawal of consent at any time may be considered invalid on the grounds of contrariety to the GDPR (Article 7).

Finally, Article 13 GDPR prescribes the information that needs to be provided by the controller (the first recipient of the sample) to the data subject (the first transferor of the sample), namely the purposes of processing for which the personal data are intended as well as the legal basis for the processing; the period for which the personal data will be stored, or if that is just not possible, the criteria used to determine that period; and the existence of the right to

withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal. One may argue that Article 13 GDPR prescribes mandatory pre-contractual and contractual duties of information. Arguably, a failure to fulfil these duties by the first recipient of the samples might entail the invalidity of the contract.

23.2 On national limits derived from the application of international and supranational law documents

23.2.1 Italy

-Limits stemming from the conflict with mandatory law

In Italy, the conflict with any mandatory rule makes a contract invalid. Therefore, the analysis of the validity of a contract on human biological samples must take into account the mandatory rules laid down in all national sources of data protection law and the GDPR. Furthermore, all Italian rules on data protection law, including the Authorizations, and the GDPR integrate the contract: they contribute to determine the effects of contracts on human tissue.

-Limits stemming from the interpretation of the Oviedo Convention

The data protection rules incorporated in the Oviedo Convention constitute the basis for the interpretation of national legislation on the matter. This argument seems to be confirmed by the fact that the Genetic Data Authorization explicitly refers to Articles 10, 11, and 12 of the Oviedo Convention, in addition to other international and supranational data protection documents i.e. the International Declaration on the Human Genome and Human Rights (Articles 2, 5 and 6), the International Declaration on Human Genetic Data (Article 10) and the CFREU (Article 21).

-Limits stemming directly from the Genetic Data Authorization

Similarly to the provision of the GDPR (Recital 156), the Genetic Data Authorization prescribes that the use of non-anonymous data is only allowed if the goals of the research cannot be achieved with the processing of anonymous genetic data. Furthermore, the Genetic Data Authorization requires that the use of genetic data and human biological samples is only allowed if the person has expressed her written consent (Article 6). The GDPR, on the contrary, does not demand the necessity of the written consent. Therefore, in Italy, the contract for the use of human tissue and its data is a formal contract because the consent must be expressed in writing.

Both the GDPR (Article 7) and the Genetic Data Authorization (Article 6) allow for consent to be withdrawn at any time. However, the effect of withdrawing consent under the Genetic Data Authorization is the destruction of the sample, unless the sample cannot be linked to an identified or identifiable person. Arguably, a contractual provision that precludes the donor of a human biological sample to withdraw her consent cannot be considered valid, because it clashes with the rules of Article 7 of the GDPR and Article 6 of the Genetic Data Authorization.

23.2.2 England

-Limits stemming from the DPA 2018

In the case of England, the structure of the DPA 2018 and its different entangled provisions with further normative references to other legal instruments, make it difficult to extract the relevant provisions that may limit the validity of contracts on human tissue.

However, from the analysis of the provisions of the DPA 2018 two main conclusions can be derived:

Firstly, the DPA 2018 does not allow the processing of genetic data for scientific purposes when such processing is likely to cause substantial distress to the data subject. This prohibition constitutes a limit to the validity of contracts on human tissue. A contract that involves the transfer of human tissue, and the processing of genetic data associated to it, is not valid if such processing causes distress to the data subject. The determination of whether or not distress may be caused to the data subject will always depend on the analysis of the particular contract at hand.

Secondly, based on the provisions of the GDPR that allow for derogations, the DPA 2018 restricts the application of certain rights of the data subject, when such rights may trump the achievement of the scientific purpose. These rights include the right to access, the right to rectification, the right to restriction of processing, and the right to object. Based on the DPA 2018 and the GDPR, a contract for the transfer and use of human tissue may legally limit these rights insofar as the use of the tissue has scientific or other purposes recognized under the GDPR. In any other circumstances, such rights may not be validly restricted.

23.3 On national limits derived from the internal system of law sources

23.3.1 Italy

The legal categories of annullability and nullity are especially relevant for the assessment of the validity of contracts on human tissue.

Regarding annullability, the category of mistake might prove useful for the analysis of cases where the original transferor of the tissue made a mistake on the nature of the contract she was concluding. The category of fraud is relevant for the analysis of cases where the person was deceived to conclude a contract, for example when the person was made to believe to transfer human tissue for purely diagnostic purposes while in reality the material was to be used for obtaining a patent which would secure considerable financial gain for the patent holder.

While the nullity of contracts on human tissue for the absence of one constitutive element (the agreement, the cause, the object and the form) arguably only rarely comes into consideration, the opposite is true for what concerns the nullity on grounds of illegality. One may think of many possible examples of contracts on human tissue, whose objects or cause might be contrary to mandatory norms, public order or good morals, e.g. a contract for the transfer of human tissue with the purpose of carrying on eugenic practices. More generally, one could argue that a contract for the transfer of human tissue in exchange of valuable consideration is illegal because of the illegality of the cause or the object (making the human body as a source of financial gain).

Mandatory norms, public order and good morals do not exclusively pertain to the realm of contract law, but are legal categories that make reference to constitutional principles or other basic principles of the political and social order or to fundamental and constitutional rights, including human dignity.

Fundamental rights that are part of this constitutional framework for the acts of disposition of the human body could be applied directly or indirectly by Italian judges in cases involving contracts on human tissue. In this regard, the application of fundamental rights through the interpretation of open norms or general clauses of private law creates a virtuous circle whereby the content of these open norms is filled with constitutional principles and fundamental rights.

In particular, the fundamental principle and supra-constitutional value of human dignity, embodied in Article 2 Cost. constitutes the basis for the constitutional recognition of new emerging values and can play a significant role in the assessment of the validity of contracts on human tissue. Specifically, human dignity could serve as a criterion for assessing the illegality of the cause and object of the contract.

There is an evident parallel between the classic limits to the validity of contracts under Italian law (mandatory norms, public order and good morals) and the limits to the acts of disposition of the human body prescribed by Article 5 C.C. (law, public order and good morals). It seems logical to assume that the modern understandings of the limits to the validity of any contract should apply in the same way to the limits to the acts of disposition of the human body, including the

disposition of human tissue. Constitutional principles, values and fundamental rights fill the content of open norms or general clauses such public order and good morals. The additional limit of the "permanent reduction of the physical integrity" included in Article 5 C.C. has also been understood in accordance to constitutional values: the notion of physical integrity should be interpreted now in relation to the constitutional value of the human health.

Article 50 C.P. and the doctrine of consent could contribute to determine the validity of contracts, for example in cases where a person has authorized, by signing a contract, a medical intervention that causes permanent damages to her health, e.g. the *inter vivos* transfer of a cornea. Both the internal and external conditions for consent to be valid apply in the determination of the validity of a contract on human tissue. The internal condition (the capacity of the person to understand the effect of the injury) finds a parallel application in the contract law doctrine of annullability of the contract because of incapacity. The external condition (the right has to be objectively alienable) has been interpreted in accordance with the constitutional notion of health – like the notion of "permanent reduction of physical integrity" under Article 5 C.C. – and the constitutional principles of solidarity and self-determination.

Regarding the prohibition of financial gain – the general principle of international and EU law according to which the human body and its parts cannot be a source of financial gain – two different positions can be found in the Italian scholarly debate.

According to a first position, the prohibition of financial gain entails: a) the general rule of gratuitousness of the acts of disposition of the human body, which prohibits economic profit from the body, its parts and its functions, and constitutes the grounds for declaring void such transactions when concluded for economic profit; b) that the human body and its parts cannot be the object of a patrimonial right.

According to a second position in Italian scholarly works, the prohibition of financial gain is only an exception to the general rule of free disposition of the human body included in Article 5 C.C. Accordingly, when the detachment of the body part does not entail a permanent reduction of the person's physical integrity, the relation between the person and the part is one with patrimonial content and can be described in terms of the possibility of fruition and exchange.

Independently of the stance one takes on these two positions, the determination of the scope of application of the prohibition of financial gain under Italian law is difficult. Italian scholars have sustained that the prohibition included in the CFREU and the Oviedo Convention is limited to the fields of medicine and biology. Work contracts in the field of sports, or for the commercial use images of the human body or for prostitution are excluded from the prohibition of financial

gain. Furthermore, this prohibition only refers to human body parts that have not been the object of transformation (e.g. fixing tissue samples in paraffin blocks). Finally, it would appear from the analysis of the Italian literature on the matter, that the prohibition of financial gain is limited to the relation between the first transferor and the first recipient of the tissue. The relation between the first and subsequent recipients are arguably not covered by this prohibition.

In the domain of the contracts for profit between the first transferor and the first recipient of human tissue, only a small number of contracts are explicitly allowed by Italian legislation: the transfer for profit of waste products and reproducible elements like teeth, hair and nails. The transfer for profit of human tissue for the purposes of scientific research and possible commercial uses thereof is not explicitly allowed nor explicitly prohibited.

In any case, in Italian scholarly works there is a prevalent trend to not recognize the validity of contracts on human tissue for profit between the first transferor and the first recipient.

Finally, regarding the analysed MTA's several conclusions can be drawn. Firstly, there is a common core to both types of MTA's. This core includes the following characteristics: a) the prohibition of obtaining economic profit from the transferred materials; b) the necessity of obtaining consent from the providing institution for the transfer of the materials to a third party; c) the prohibition of using the transferred materials on humans and; d) the recognition of property rights on the materials. Secondly, it is noticeable how both contracts do not include any provisions regarding the consent of the original source of the materials or the protection of the data associated to the materials.

23.3.2. England

In England & Wales, the framework for the determination of the limits the validity of contracts on human tissue can be distilled from the interaction of several law and governance sources. The main statutory instrument on the removal, use and storage of human tissue is the Human Tissue Act 2004. The HTAct (s1 (1)-(3)) regulates the activities that can be lawfully performed with appropriate consent, including the storage and use of relevant material that comes from bodies of living persons. Schedule 1 of the HTAct lists the purposes for which it is necessary to obtain consent when carrying an activity described in s1 (1)-(3). The following scheduled purposes are relevant for the subject matter of this book, in particular, because they could be achieved via the conclusion of a contract on human tissue: obtaining scientific or medical information about a living person which may be relevant to another person; public display; research in connection with disorders or the functioning of the human body and, transplantation. The HTAct (s1 (4)-(9)), however, excepts from the requirement

of consent, the use and storage of relevant material from a living person for the purposes of research in connection with disorders or the functioning of the human body, provided that the research is ethically approved and it is to be carried in a way that the person conducting the research is not in possession, or likely to come in possession of information from which the person from whom the material has come can be identified.

This exception is in line with the provisions of the General Data Protection Regulation that allow the processing of data without the consent of the person for achieving scientific purposes when the necessary safeguards for the personal information of the subject have been put into place.

Although the whole normative body of the HTAct (with certain exceptions) is built around the idea of consent, the HTAct does not define this notion. It is the HTA Code of Practice A on Consent that indicates that appropriate consent must come from the person entitled to consent and indicates that its form of expression is irrelevant for its validity unless the HTAct requires otherwise. Therefore, the form of expression of consent for the conclusion of contract on human tissue does not require any specific form, although it would be preferable to obtain it in writing. Moreover, according to Code of Practice A, it is possible for the person to attach conditions on consent to restrict the type of activities allowed to be performed with the tissue. Such conditions would place limits not only to the contract between the first transferor and the first recipient, but also, to the possible future contracts between the first and further recipients of the tissue.

The HTAct prescribes two types of restrictions of activities on human tissue that arguably should also apply to contracts on human tissue. The first type of restriction (section 8(1) HTAct) indicates that a person commits an offence if she uses or stores material for a purpose different than a qualifying purpose. The second type of restriction refers to the general prohibition of commercial dealings in human material for transplantation(s 32(1)). Accordingly, a contract concluded for the purpose of dealing commercially with human tissue for transplantation should be considered invalid.

Since the HTAct does not regulate consent for the purposes of removal of human tissue, the legal regime for this purpose can be found in the common law rules, the Mental Capacity Act and the Department of Health guide to consent. Particularly relevant are the requirements of capacity, voluntariness and appropriate information. Arguably, if one of these requirements is missing, the contract should be declared invalid.

This book identified seven headings of illegality and public policy that could constitute grounds for challenging the validity of contracts on human tissue:

contracts amounting to a legal wrong, contracts to commit a crime, contract to commit a civil wrong or perpetrate fraud, agreements which are in themselves lawful but are used for an unlawful purpose, agreements in which the method of performance is unlawful, contracts restricting personal liberty, and contract contrary to good morals.

In particular, these seven headings are relevant for at least four aspects of the subject matter of this book. First, for the determination of the limits to the validity of contracts on human tissue stemming from statutory sources, as in the cases of contracts amounting to a legal wrong and contracts to commit a crime in relation to the normative provisions of the HTAct (e.g. section 32 HTAct). Second, for the analysis of other relevant legal sources that complement the legal regime on the removal, use and storage of human tissue, and in particular for the analysis of the contracts to commit a civil wrong or perpetrate fraud in relation to the legal regime of consent under common law. Third, for the assessment of the validity of contracts on human tissue when the purposes of the contract are not explicitly or implicitly regulated by law (e.g. the use of human tissue for artwork). Fourth, for the role that the notion of good morals may play when deciding the validity of contracts with a highly disputed moral content (e.g. contracts for the sale of human tissue).

Regarding the effect of fundamental rights on the validity of contracts on human tissue, it seems that human dignity and other fundamental rights could have a role in the determination of such limits. From the position of courts and scholars alike it can be derived that the HRA has at least an indirect effect (in one of its multiple variations) on disputes between private parties, including disputes arising from contracts on human tissue. Similarly, from the harmonic reading of the HRA 1998 and the HTA Codes of Practice A and E, it seems possible that the principle of human dignity can constitute the grounds for the identification of limits to these of type of contracts.

Finally, from the analysis of the model contracts it can be derived that, although some clauses might clash with the legislation regulating the rights of the original transferors of the tissue, these contracts comply with the limits identified and described in this book. However, it would be desirable that the inclusion of clauses for the protection of the rights of the first transferor of the tissue becomes a generalized contractual practice in the drafting of contracts, with or without, commercial purposes.

23.4 Comparative analysis of the limits to the validity of contracts on human tissue

23.4.1 On contracts on human tissue explicitly prohibited or allowed by law

Both in Italy and England there are certain types of contracts on human tissue explicitly prohibited by law when the intention is to use the tissue for transplantation. In Italy, the transfer of tissues and cells for grasp or transplant is prohibited if performed for remuneration or for the purposes of commercialization.

In England, the list of activities explicitly prohibited by law is more detailed than in Italy and includes the following commercial dealings of any material that consists or includes human cells if intended for transplantation: 1) giving or receiving a reward for the supply of, or the offer to supply any material; 2) seeking to find a person willing to supply any such material for reward; 3) offering to supply any material for reward; 4) initiating or negotiating any arrangements involving the giving of a reward for the supply of, or for an offer to supply, any material; 5) taking part in the management or control of a body of corporate or incorporate persons whose activities consist of or include the initiation or negotiation of such arrangements. A contract that includes any of the aforementioned activities should therefore also be considered as prohibited by law.

However, under English law there are two notorious exceptions to the prohibition of commercial dealings on human tissue. According to the first exception –typical of the common law tradition– if a human skill is applied to the material it then becomes an object of property and can therefore be also the object of commercial dealings. According to the second exception, cell lines, as any other material created outside the body, are excluded of the prohibition of commercial dealings.

Although in both legal systems there is a prohibition of commercial dealings on human tissue, the ban is wider in scope in Italy, since it does not allow for any of the aforementioned exceptions. Furthermore, since the application of human skill on human tissue under English law would enable a person to escape the scope of application of the prohibition of commercial dealings, one could argue that such prohibition only applies, *prima facie*, to contracts between the first transferor and the first recipient.

23.4.2 On the general limits to the validity of contracts on human tissue

-Stemming from supranational fundamental rights sources

In Italy the relevant norms of the UDHR, ECHR, Oviedo Convention and CFREU may constitute limits to the validity of contracts on human tissue. In the English legal system, arguably only the provisions of the HRA 1998 and the Oviedo Convention have an effect for on interpretation and determination of the limits to the validity of such contracts.

-Stemming from EU supranational sources: data protection law

Because of the complete direct effect of EU Regulations, the GDPR imposes direct and indirect limits to the validity of contracts on human tissue both in England and Italy. In particular, contracts that involve the processing of personal data are bound to the principles of the GDPR. The direct limits relate to the *consent* of the person for the processing of data. The indirect limits include the creation of certain pre-contractual *information* duties regarding the contracts on human tissue that involve the processing of data. Both types of limits apply for all types of contracts that encompass any of the activities that fall within the scope of the aforementioned regulation.

More specifically, the provisions of the GDPR limit –in different ways and on various grounds– the conclusion of contracts on human tissue that involve the processing of genetic or health data. Regarding the direct limits, a first limit can be deduced from the Article 9.2 GDPR, which only permits the processing of these types of data if explicit consent of the data subject is given for one or more purposes. From this provision, it necessarily follows that consent of the data subject (first transferor of the tissue) is required for any contract involving the processing of health and genetic data. The requirement of consent applies without distinction for both gratuitous and non-gratuitous contracts. Other direct limits can be deduced from Article 7 GDPR, which prescribes the conditions for consent for the processing of data. According to this provision, when consent is given in the context of a written declaration that also involves other matters than the processing of data, the request for the consent of the data subject (first transferor of the tissue) should be presented in such a way that it is clearly distinguishable from the other matters. Another limitation to contracts on human tissue stemming from Article 7 GDPR is the right of the data subject (first transferor) to withdraw her consent at any time. Contractual clauses limiting this right of withdrawal cannot be included in contracts for the transfer of human tissue that entail the processing of health and genetic data.

Regarding the indirect limits, Article 13 GDPR requires the data controller (first recipient of the tissue) to provide the data subject with the following information: the purposes of processing for which the personal data are intended as well as the legal basis for the processing; the period for which the personal data will be stored, or if that is just not possible, the criteria used to determine that period; and the existence of the right to withdraw consent at any

time, without affecting the lawfulness of processing based on consent before its withdrawal. Depending on the legal system, the obligation to provide this information could constitute the grounds for pre-contractual duties or even for the mandatory inclusion of contractual clauses as in the case of the criteria used to determine the storage period of the data.

In what concerns the matters covered by the GDPR, the scope of protection and the limits to the validity of contract on human tissue are identical for both the legal systems of Italy and England.

-Stemming from the rules and doctrine of the invalidity of the contract

The limits to the validity of contracts on human tissue between the first transferor and the first recipient stemming from the rules and doctrine of the invalidity of the contract vary significantly from Italy to England. One possible reason for this divergence may be found in the fact that while in Italy the invalidity of the contract is essentially regulated by the general private law norms included in the civil code, in England the doctrines of illegality and public policy have been developed by the common law.

There are points of contact and points of divergence between the limits to the validity of contracts on human tissue arising from the grounds of invalidity of contracts in Italy and England. Although the terminology used in both legal systems is different, perhaps the strongest convergence arises from the fact that in both legal systems a contract is illegal if its purpose (in England) or object (in Italy) is prohibited by statute (in England) or mandatory law (in Italy). In fact, it is from this common characteristic that one could derive the illegality of contracts stemming from the applicability of provisions of the GDPR and other statutes.

Moreover, in both legal systems the category of good morals could play a role in the determination on the validity of contracts on human tissue, with the proviso that in England the concept of good morals does not include fundamental rights, as it is the case in Italy. Although only in the Italian legal system it is possible to directly apply constitutional principles and fundamental rights via the general clauses of private law of public order and good morals for the determination of the validity of contracts on human tissue, in England it is possible to interpret the content of the contract in the light of the rights enshrined in the ECHR, and according to some scholars, even declare the unenforceability of certain contractual clauses.

Finally, because of the relatively open character of the notions of public order and public policy in both legal systems, one could argue that –in the determination of the validity of contracts on human tissue– both English and Italian judges have a broad range of manoeuvre and flexibility to navigate

between different legal categories available and determine the most appropriate legal solution on a case by case basis.

-Stemming from the protection of human dignity and other fundamental rights

To date, there is no case law on the relation between the protection of fundamental rights and the validity of contracts on human tissue in any of the studied legal systems. However, from the general functioning and scope of the system of protection of fundamental rights in each of these countries, it is possible to imagine – *in abstracto* – how, and to what extent, fundamental rights can have a bearing in the determination of the limits to the validity of contracts on human tissue.

In Italy, since scholars and courts admit the direct and indirect (through the interpretation of open norms of private law) horizontal effect of fundamental rights on private relationships, the recognition of human dignity as a (supra)constitutional principle and fundamental right has practical implications for the determination of the limits to the validity of contracts on human tissue: a contract that is contrary to human dignity could be considered invalid on the grounds of its contrariety to public order and good morals.

In England, the principle of human dignity cannot be found in the wording of the ECHR or the HRA 1998. However, because human dignity constitutes the implicit foundation of the HRA 1998, and because the obligations of English courts to take into account the case law of the ECtHR, the principle of human dignity may play a role in the determination of the limits to the validity of contracts on human tissue. In addition to the principle of human dignity, the right to respect for private life (in relation to personal data) enshrined in the HTA 1998 may constitute a limit to the validity of contracts on human tissue.

In England, the respect to the principle of dignity in relation to the use of human tissue can, additionally, be derived from the wording of the HTA Code of Practice A on Consent. This code prescribes that dignity should be one of the guiding principles that persons involved in the use of human tissue should follow. Such principle entails, according to the same code, the protection of the privacy of the person.

-Stemming from the relation between the protection of physical integrity and health, and consent

The limits to the validity of contracts on human tissue arising from the protection of physical integrity and health on the one hand, and the legal regime on consent on the other, are very different in the Italian and English legal system. These differences arise from the way each of these legal systems affords protection to these rights. While in Italy, the right to health – which includes the

protection of physical integrity – is explicitly considered as a fundamental right and collective interest by Article 32 of the Constitution, in England the protection of physical integrity stems from the principles of personal autonomy, self-determination and consent. Furthermore, while in Italy the "permanent reduction of physical integrity" is included in Article 5 C.C. as a direct limit to the validity of the acts of disposition of the human body (which include human tissue), in England the removal of tissue from living persons (which affects physical integrity) is regulated by the rules of common law, the Mental Capacity Act 2005, and the guidelines issued by the Department of Health.

Comparing the limits to the validity of contracts stemming from the relation between the protection of physical integrity and health, and consent, in the legal systems of Italy and England it is possible to observe some substantive similarities and some formal differences. The most striking substantive convergence between the two legal systems is that in both the relationship between the rights to bodily integrity and consent stems from the more abstract principle of personal freedom or personal autonomy. This convergence somehow blurs the more formal distinction between a legal system where personal integrity and health are protected via constitutional rights (Italy) and one where the right to bodily integrity derives from a liberties-based approach (England). This convergence seems to be confirmed by the idea that in both legal systems a contract on human tissue that lacks the consent of the first transferor should be considered, *prima facie*, as illegal. In both legal systems there is a close link between non-contractual liability and the illegality of the contract. In England, this relationship arises from the torts of negligence and battery, and in Italy from Article 50 C.P. in connection with general tort law.

Finally, there is a clear distinction in the way both legal systems afford statutory protection of consent in relation to the use of human tissue. In England, the HTAct, which regulates human tissue, is essentially based on the notion of consent. In Italy, the relation between consent and the use of human tissue only becomes apparent through the interpretation of Article 5 C.C. in the light of constitutional rights and/or Article 50 C.P.

23.4.3 On the limits to the validity of non-gratuitous contracts between the first transferor and first recipient

In the Italian and English legal system, the debates around the possibility of concluding non-gratuitous contracts on human tissue have two different gravitational centres. In Italy, the debate has its contemporary origin in the provisions of the CFREU and Oviedo Convention that prohibit financial gain from the human body and its parts, as such. In England, since both the CFREU and the Oviedo Convention are not directly applicable, the debate focuses, to a large extent, on the inexistence of property rights on human tissue. One could also

venture the idea that such differences in the debate arise from the differences in the legal relevance of fundamental rights in both legal systems. That being said, the aforementioned considerations, i.e. the prohibition of financial gain and the inexistence of property rights, are only the general rule in both legal systems, but some additional characteristics of the debate somehow soften such general rules. In Italy, for example, a scholarly position maintains that it is possible to speak of property rights of fruition and unlimited disposition of the detached parts of the human body and in England, some scholars have also considered human dignity as an element to be considered when analysing the validity of contracts on human tissue.

23.4.4 On the limits to the validity of contracts between the first recipient and subsequent recipient

The limits to the validity of these contracts stems, essentially, from the requirements of consent for the storage and use of human tissue and the data associated to it.

In this regard, the GDPR provides a framework of analysis applicable to both Italy and England. According to the GDPR, when the further processing of the data associated to a tissue sample is done for achieving purposes in the public interest or scientific purposes, a new consent from the data-tissue source is no longer necessary (Article 5(1)b GDPR). However, two conditions must be met in order to use the data without a new consent. Firstly, technical and organizational safeguards that respect the principle of data minimisation must be included for the protection of the rights of the first transferor of the tissue (Article 89(1)), e.g. pseudonymisation measures. These safeguards are to be in place by each Member State. Secondly, it must be assessed whether anonymous data cannot be used instead (Recital 156 GDPR). Particularly, in relation to genetic data, the GDPR includes a specific provision that prescribes these type of data can be further processed for research purposes without the need of a new consent (Article 9.2 GDPR).

If the purpose of a contract between the first and subsequent recipients does not fall within the exceptions to consent of the GDPR there are two possible scenarios. Either the first transferor of the tissue has explicitly consented to further transfers, or either she has not. In the first case, the subsequent transfers would be valid, in the second case, such transfers would not be legally possible.

For these reasons, in both Italy and England when the first recipient intends to transfer human tissue to further recipients for purposes different than the ones exempted in the GDPR, it is always necessary to obtain the consent of the first transferor.

Regarding the national limits to these types of contracts there are some formal and substantial differences between England and Italy.

A first formal difference stems from the fact that, unlike Italy, England has a specific statute aimed at regulating the use of human tissue (the HTAct). Although the HTAct is built around the idea of consent, it provides a series of exceptions to the consent of the first transferor. One of these exceptions prescribes, in line with the GDPR, that consent is not necessary for the use and storage of relevant material that come from living persons for the purposes of research in connection with disorders or the functioning of the human body (section 1(4)(9) HTAct). However, for this exception to apply two further requirements must be met: 1) Research must be approved by a recognized research ethics committee (REC) according to the regulations made by the Secretary of State. However, according to the Code of Practice E, a university ethics committee does not qualify, for the purposes of the exception, as a recognized REC. 2) Research must be carried out in circumstances such that the person carrying out is not in possession, and not likely to come in possession of information from the original source of the tissue.

The Italian legal system is more severe in the regulation and does not provide for a similar exception. On the contrary, there are further requirements for the use of genetic data. In fact, according the Genetic Data Authorization, genetic data can only be used if the person has previously expressed her written consent (Article 6). Nonetheless, similarly to England, this Authorization prescribes that the use of non-anonymous data must be preceded by the preparation of a research project that includes the necessary measures to ensure the confidentiality of the information of the original transferor of the issue (Article 4.2). Additionally, for the use non-anonymous data and tissue samples, in the same line as the GDPR, it is necessary to first assess whether or not anonymous data and tissue cannot be used instead (Article 3.1 Genetic Data Authorization).

Therefore, while in England, the first recipient could further transfer the tissue to subsequent recipients without the consent of the original source (first transferor) for the purposes excepted in the HTAct, in Italy consent will always be necessary for such transfers and for all purposes. In England, for any other purposes, consent will also be necessary.

Although the legislation on this matter seems to be more demanding in Italy, the Data Protection Act in England provides an additional protection mechanism for the rights of the original transferor of the tissue. According to section 19(2) of this Act, processing is not according to Article 89(1) GDPR, if it is likely to cause to the data subject substantial distress or damage. For this reason, contracts between the first recipient and subsequent recipients find in this article a further limitation.

Finally, regarding the different clauses included in the different MTAs in Italy and England, two main differences can be identified. Firstly, Italian MTAs, surprisingly, are more prone to recognize property rights on human tissue, albeit the contract clauses prohibit any financial gain from the tissue transfers. Secondly, strikingly, English MTAs include several clauses with references to the consent of the original transferor of the tissue and the protection of her data rights. In Italy, such clauses are conspicuously absent.

23.5 This book's position

23.5.1 On consent

This book argues that the validity of informed consent lies on the autonomy of the person and its genuine communication. Therefore, it would be acceptable to allow broad consent for future and still undetermined studies, insofar as the individual´s rights on her tissue are still protected while conducting research, e.g., the confidentiality of data associated to the tissue sample, the right to not know and the obligation of the researchers to communicate to the aforementioned delegated third party the types of studies that are being carried on tissue samples.

It should be underlined that a broad consent for all types of research is not ethically acceptable. It should be the donor who decides, accordingly to the modality of the research and interests involved in it, the type of consent that she is willing to give: specific consent for one particular research project; specific consent for a particular research project with the possibility open to the researchers of asking for new consent in case they intend to carry on a different type of research; consent partially restricted to specific types of research, e.g., research on cancer; broad consent for present and future research for any kind of research with an anonymized or codified sample and; broad consent for present and future research with an identified sample.

Independently of the type of consent, in order for consent to be considered valid, it is of vital importance that the person receives all the necessary and appropriate information.

Researchers should inform, when possible, and depending on the type of research the following aspects: the voluntary character of the extraction and further analysis on the tissue sample, the number and quality of the samples that will be obtained, the risks of the procedure, the risks that the handling of the information involves, the information that could be obtained from the analysis and the methods to handle it (whether or not the tissue samples will be codified or anonymized), the intended duration of the use and storage of the obtained data, the confidentiality of the information, the importance for relatives of the possible outcome of the analysis on the sample (e.g, in the case of genetic

research), who will be able to access that information (relatives, researchers, the persons itself, third parties), in case of unexpected findings the right of the person to know and to not know about them, the availability of genetic counselling, the intended use and disposal of the sample during and after the research (e.g. transfer to third parties, storage for future research, destruction of the sample once the study has ended, human implantation), the potential commercial use of the sample and the data associated to it or to the research results, and the research sponsor.

Under a contractual model for the regulation of rights and duties on human tissue, the aforementioned information could be incorporated to the contract in the form of contractual clauses for the protection of all the parties involved.

23.5.2 On the protection afforded to the first transferor's data

One of the main arguments against anonymization is that it harms the person´s autonomy because she loses control over the samples once they have been anonymized.

The issue of autonomy should be analysed *ex ante* and not *ex post* the extraction of the tissue sample. The transferor is not threatened in her autonomy if the election of anonymizing her tissue sample is the result of an informed and conscious decision. If the sample was initially obtained for the purposes of research the decision of anonymizing the sample should be taken prior to its removal. However, if the sample was taken as a consequence of a medical treatment and it is intended to be used in research it would be advisable to look for the consent of the original transferor, and if that is not possible, then rendering the sample completely anonymous would be the best possible practice.

The idea that the donor should have in any case certain degree of influence over her samples answers to a paternalistic vision. From an ethical point of view, nothing stands in the way of the donor's decision to not knowing the results of the research. However, if the person expresses her desire of knowing the research outcome it will be unethical to anonymize the sample, because in this case his autonomy would be in fact harmed. In this situation, encoding the sample would protect both the person´s right to know and the confidentiality of the data associated to the sample. The use of an identified sample for research is most of the times difficult to accept from an ethical point of view for the high risks that it presents to the privacy of the donor, but should it remain identified, it is up to the researcher to justify the reasons why research cannot be carried on a coded or anonymous sample.

In addition, the degree of conflict when a member of the family or any other third party with a legitimate interest wants to know the research findings will also

vary depending on the type of sample. Undoubtedly, when the material is anonymous or anonymized, not even the donor will have access to the research results, and as a consequence it would be illogical to suppose that a third party could or should be able to access them. The same can be said when the donor has expressed her desire to not know. However, that is not the case when dealing with identified samples and the person has stated her desire to know the results.

Moreover, it is clear that certain types of research would have their chances for success limited if they were carried out on anonymous or anonymized samples. However, scientific progress is not a mandatory goal. A slower rhythm in the development of science is more desirable than one that threatens essential ethical and societal values.

Taking into account the aforementioned consideration it would be desirable to allow the person to withdraw her consent when research is carried on identified samples since they still contain the personal information of the donor and as a consequence research on her tissue could be considered as a form of experimentation on humans.

In the case of anonymous or anonymized samples the right to withdraw consent is in practice impossible since they have been completely unlinked from the donor's personal information.

Furthermore, to protect the person's autonomy it is necessary to grant her the possibility of choosing which kind of process will be applied on her sample, even if this undermines scientific progress. It is the donor who is legitimized to decide whether her personal information should remain associated to her samples or not. If asking for her consent is not possible in practice, it would be desirable to irreversibly anonymize her sample in order to protect the security and confidentiality of the data.

Even if it is true that anonymization does not completely protect the individual from the possible risks associated with the research, it is also true that it seems to be the best possible option to safeguard the donor's rights.

Finally, many of the described conflicts could be avoided if contractual clauses are included to determine the level of protection of the sample. It would be the original transferor of the tissue, the one called to decide, *ab initio*, the level of identification of her samples.

23.5.3 On the validity of non-gratuitous contracts between the first transferor and the first recipient

The arguments against the sale of human tissue have a strong moral component and entail, to greater or lesser degree, a form of legal paternalism. Broadly speaking, most of the arguments against the sale of human tissue for research are based on one or more of the following considerations: 1) The people who have the strongest interest in selling their tissue are the economically disadvantaged ones. One may argue that the sale of tissue by an individual in financial distress is not based on freedom, but on (economic) coercion. And one may argue that allowing such sales increases the inequality between the rich and the poor; 2) Economic remuneration for human tissue commodifies the person and is contrary to human dignity: therefore, a market for human tissue degrades the person; 3) The market logic in the transfer of human tissue casts out the principles of altruism and solidarity, which would be safeguarded by a system that prohibits the sale of tissue and only allows tissue donations or other types of gratuitous transfer of tissue.

All the three aforementioned arguments are, to a certain degree, paternalistic. The analysis of each of these arguments has also shown that they do not sufficiently justify imposing a prohibition on the conclusion of such contracts. Instead of such a ban, less intrusive forms of protecting the autonomy of the first transferor of human tissue –while at the same time respecting value-pluralism– could be derived from contract law, in general, and contract drafting, in particular.

The analysis of three different cases involving acts and contracts on human tissue has also shown how the conclusion of non-gratuitous contracts on human tissue can work as a mechanism of governance through contract (e.g. PXE) that is desirable from a practical and a theoretical perspective.

From a theoretical perspective, allowing such contracts would expand the available range of valid individual choices in a manner that is consistent with the conceptions of autonomy and value pluralism endorsed by this book.

From a practical perspective the advantages are numerous: the first transferor of tissue would enjoy at the same time the protection provided by all statutory and contractual provisions; the relation between the first transferor and the transferees could be rebalanced via contractual mechanisms; the interaction between mandatory norms and default rules could achieve a strengthened protection of the person's autonomy; the first transferor could obtain a direct economic benefit from the transfer of the tissue; the parties could agree on different contractual clauses and conditions for the use of tissue in research and

finally, the conclusion of non-gratuitous contracts would be consistent with the requirement of informed consent.

23.6 Recommendations

Following the aforementioned conclusions, this books proposes the following recommendations:

1) It is desirable to regulate, via contract law legislative provisions, the tissue transfers for the purposes of research.
2) This regulation should place on the first recipient, prior the conclusion of the contract, a clear set of information duties towards the first transferor of the tissue.
3) The information that should be provided to the first transferor includes the following:

    - Regarding the **tissue samples**: a) the voluntary character of the extraction and further analysis on the tissue sample; b) the number and quality of the samples that will be obtained and c) the intended use and disposal of the sample during and after the research (e.g. transfer to third parties, storage for future research, destruction of the sample once the study has ended, human implantation).
    - Regarding the **risks of research**: a) the risks of the procedure and b) the risks that the handling of the information involves.
    - Regarding the **information associated** to the tissue samples: a) the information that could be obtained from the analysis and the methods to handle it (whether or not the tissue samples will be codified or anonymized); b) the intended duration of the use and storage of the obtained data; c) the confidentiality of the information; d) the importance for relatives of the possible outcome of the analysis on the sample (e.g, in the case of genetic research); e) who will be able to access that information (relatives, researchers, the persons itself, third parties) and; f) in case of unexpected findings the right of the person to know and to not know about them.
    - The potential **commercial use** of the sample and the data associated to it or to the research results, and the research sponsor.
    - The availability of **genetic counselling**.

4) Article 13 GDPR, which already includes some of the items listed above, should be expanded to include them all.
5) At least the following items of the list above should also be included as mandatory contractual clauses for the transfer of tissue: a) the number

and quality of the samples that will be obtained; b) the intended use and disposal of the sample during and after the research; c) the intended duration of the use and storage of the obtained data; d) the confidentiality of the information and who will be able to access that information; e) the potential commercial use of the sample and the data; f) information on whether or not financial gain is expected to be derived from the research on the tissue sample and g) the possibility of transferring the tissue to other parties.

6) This regulation should allow the conclusion of sales and other non-gratuitous contracts on human tissue between first transferor and the first recipient. Following this recommendation would entail the elimination of the prohibition of financial gain contained in Article 3 CFREU and Article 21 of the Oviedo Convention.
7) The proposed contract law regulation should include mandatory and default rules for contracts between the first transferor and first recipient.
8) A necessary mandatory rule should prescribe that prior to the conclusion of the contract, the first transferor must assess weather or not anonymous information can be used instead of personal information.
9) A possible default rule should indicate that, once it has been established that anonymous information cannot be used, the sample should be codified or pseudoanonymized.
10) The proposed regulation should allow the first transferor and the first recipient to deviate from the previous rule.
11) Another possible default rule should prescribe the gratuitous transfers of tissue for all types of contracts when the purpose of the research is not commercial, but for example, strictly academic.
12) The proposed regulation should allow deviating from the previous rule.
13) The first transferor of the tissue should be free to decide, once it has received all the appropriate information, whether to give a specific or a broad consent for the research on her tissue.
14) Regarding contracts between the first recipient and subsequent recipients, mandatory rules should require that, when technically possible, the firs recipient should warrant that valid consent has been obtained according to all applicable laws.
15) Regarding contracts between the first recipient and subsequent recipients, mandatory rules should require that such contracts must conform to the limits set in the original consent of the first tissue transferor.

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Chapter 24

AGENDA FOR FURTHER DEBATE

CHAPTER 24 Agenda for further debate

The debate on the ethical and legal implication of the unbalance between downstream players (first transferors of tissue) and upstream players (first and subsequent recipients) in the chain of transfers of human tissue is not new, and has given rise to a multiplicity of arguments both in favour and against the current model. However, those arguments can be generally placed in one of the two following sets of arguments.

The first set relates to a legal-ethical debate that can be formulated in terms of the tension between autonomy and paternalism: are individuals formally and substantively free to sell their tissue or, on the contrary, should the State and the law intervene in order to prevent individuals from selling their tissue as this is considered to be prejudicial to their own interests or rights?

The second set of arguments concerns the practical and economic advantages and disadvantages of allowing markets for human tissue (e.g. whether or not a market for human tissue enhances research, or whether or not such a market increases the offer of human tissue).

Since this book was not primarily concerned with the economic efficiency of contracts but their validity, the arguments against and in favour of non-gratuitous contracts based on these practical and economic advantages were not discussed. It would be interesting to analyse from an economics and law perspective, for example, the utility of allowing the conclusion of non-gratuitous contracts in the whole chain of transfers of human tissue, from the original source until industry.

Some scholars have sustained that the current legal regime on the use of human tissue has negative consequences at both the individual and the societal level. At the individual level, the claim for the protection of human dignity leaves the initial donor in a position where she is not entitled to receive any of the economic benefits arising from her tissue. It has been argued that at the societal level the consequences are even more frightening: the current legal regime reduces product development and research, it adversely affects Member States' health care systems, it is leading to what has been termed "accumulation by dispossession" of the common genetic information, and impairs equitable access to knowledge and genetic resources.

In order to solve the negative consequences at the individual level, this book explored the possibility of allowing markets for human tissue from the very first stage by accepting the conclusion of non-gratuitous contracts between the first transferor and the first recipient. This scenario could solve some of the adverse

consequences by permitting the first transferor to participate in the economic benefits derived from the use of her tissue.

However, a different approach that transcends the purely economic and individualistic levels could be taken into account to address the possible negative consequences at the societal level and to discuss the legitimacy and legality of contracting on human tissue. Such approach could be placed at the core of a different scale of justice: global social justice.

A personal academic intuition suggests that the idea of the commons could work as an essential element for the development of a theoretical framework to guarantee, based on social justice requirements, global access to knowledge (and its benefits) and to the use of genetic resources. It remains to be seen whether or not this intuition can be confirmed. In any case, further research on this matter is most needed.

ANNEXES

ANNEXES

ITALIAN MTAs

UniFi MTA

Accordo per il Trasferimento di Materiale di _____ composti e _____ strutture a scopo di ricerca.

Il presente Accordo è stipulato da e tra (1) L'Università di _____, con sede in, _____, _____, ivi rappresentata dal Professore _____, di seguito denominato "TRASFERENTE"; e L'Università/Ente _____, con sede in Via _____ , _____, ivi rappresentata dal _____, di seguito denominato "RICEVENTE"; che sono inoltre denominati singolarmente "PARTE" o collettivamente "PARTI".

Il TRASFERENTE chiede al RICEVENTE e il RICEVENTE conviene quanto segue prima che il RICEVENTE riceva il MATERIALE:

1. Il TRASFERENTE acconsente a trasferire al RICEVENTE sotto indicato il seguente MATERIALE: _____ composti e _____ strutture. Il MATERIALE non include: (a) MODIFICHE, o (b) altre sostanze create dal RICEVENTE utilizzando il MATERIALE che non siano MODIFICHE in senso stretto.

2. Tale MATERIALE è di proprietà del TRASFERENTE ed è reso disponibile come servizio alla comunità scientifica.

3. QUESTO MATERIALE NON DEVE ESSERE UTILIZZATO SUGLI ESSERI UMANI.

4. Il MATERIALE sarà utilizzato solo a scopo di ricerca dal RICEVENTE nel suo laboratorio, per il progetto di ricerca di seguito descritto. Il MATERIALE non sarà utilizzato a scopo di lucro, per esami, produzione o vendita, per la quale potrebbe essere obbligatoria una licenza di commercializzazione. Il RICEVENTE acconsente a rispettare norme e regolamenti applicabili al PROGETTO DI RICERCA e alla manipolazione del MATERIALE.

5. Tale MATERIALE sarà utilizzato dal RICEVENTE solamente in relazione al seguente progetto di ricerca ("PROGETTO DI RICERCA") descritto come segue (Utilizzare una pagina in allegato, se necessario):

6. Il MATERIALE sarà utilizzato unicamente per l'insegnamento e a scopo di ricerca senza fini di lucro.

7. Il MATERIALE non sarà successivamente distribuito a terzi senza il consenso scritto del TRASFERENTE. Il RICEVENTE riferirà ogni richiesta inerente il MATERIALE al TRASFERENTE. Nella misura in cui siano disponibili delle scorte, il TRASFERENTE acconsente, secondo un accordo a sé stante, in forma di Lettera semplice, a rendere il MATERIALE disponibile per altri scienziati unicamente ai fini dell'insegnamento o a scopo di ricerca senza fini di lucro.

8. Le PARTI concordano sul fatto che tutti i diritti, titoli e interessi comunque derivanti da eventuali invenzioni, know-how, materiali, sostanze e altri prodotti concepiti o generati dal RICEVENTE (sia brevettabili che non) e relativi al MATERIALE o al suo utilizzo (INVENZIONI) siano conferiti in egual misura al TRASFERENTE e al RICEVENTE. Le PARTI acconsentono a

negoziare un accordo di comproprietà che specificherà i diritti e i doveri di ciascuna PARTE in relazione all'uso, lo sfruttamento e la protezione delle invenzioni comuni. Il RICEVENTE mantiene la proprietà di: (a) MODIFICHE (fatta eccezione per quanto segue: il TRASFERENTE mantiene i diritti di proprietà del materiale ivi incluso), e (b) quelle sostanze create tramite l'uso del MATERIALE o delle MODIFICHE. Qualora sia (a) che (b) risultino dagli sforzi collaborativi del TRASFERENTE e del RICEVENTE, la comproprietà può essere negoziata. In base a una lettera di esecuzione separata dal presente Accordo (o almeno un accordo di protezione dei diritti del TRASFERENTE), il RICEVENTE può distribuire le MODIFICHE ad organizzazioni no profit ai soli fini della ricerca e dell'insegnamento.

9. Il RICEVENTE si impegna a riconoscere la fonte del MATERIALE in tutte le pubblicazioni che riportano l'uso dello stesso. Qualora il risultato frutto di esperimenti sia disponibile per la pubblicazione, il manoscritto deve essere preparato congiuntamente da entrambe le parti in base a mutuo accordo. In ogni presentazione o pubblicazione scritta riguardante il materiale fornito, il RICEVENTE riconoscerà il contributo del TRASFERENTE a tale Materiale di Ricerca salvo diversa richiesta del TRASFERENTE. Ogni comunicazione orale fatta dal TRASFERENTE al RICEVENTE deve essere riconosciuta come CONFIDENZIALE da una comunicazione scritta inviata al Ricevente entro dieci (10) giorni dalla data della comunicazione orale. Il RICEVENTE può pubblicare o rendere altrimenti noti i risultati del PROGETTO DI RICERCA, ma qualora il TRASFERENTE abbia comunicato al RICEVENTE informazioni CONFIDENZIALI tale divulgazione pubblica può avere luogo solo dopo che il TRASFERENTE abbia avuto trenta (30) giorni per rivedere la divulgazione proposta per determinare se essa comprende informazioni RISERVATE che possono anche essere brevettate.

10. Qualsiasi materiale consegnato ai sensi del presente Accordo è inteso essere di natura sperimentale e può avere proprietà pericolose. Il TRASFERENTE NON RILASCIA ALCUNA COMUNICAZIONE O GARANZIA, DI NESSUN TIPO, ESPLICITA O IMPLICITA. NON VI SONO GARANZIE ESPRESSE O IMPLICITE DI COMMERCIABILITÀ O IDONEITÀ PER UN PARTICOLARE SCOPO, O CHE L'USO DEL MATERIALE NON VIOLI BREVETTI, COPYRIGHT, MARCHIO, O ALTRI DIRITTI DI PROPRIETÀ. A meno che non sia proibito dalla legge, il Ricevente si assume ogni responsabilità per richieste di risarcimento danni nei suoi confronti da parte di terzi che potrebbero derivare dall'uso, stoccaggio o smaltimento del Materiale, salvo che, nella misura consentita dalla legge, il TRASFERENTE sia responsabile verso il RICEVENTE quando il danno è causato da negligenza grave o comportamento doloso del Trasferente.

11. Il RICEVENTE acconsente ad utilizzare il MATERIALE in conformità a tutte le leggi e le normative vigenti.

12. Il MATERIALE è trasferito a titolo gratuito, o con una tassa di trasmissione facoltativa esclusivamente per rimborsare il TRASFERENTE per i suoi costi di preparazione e di distribuzione. Qualora sia richiesto un pagamento, l'importo sarà indicato qui: [inserire importo] nessuno

13. Il presente Accordo entra in vigore all'atto della firma delle PARTI.

14. Il presente accordo è concluso per un periodo indeterminato. Ciascuna delle parti può recedere dal presente Accordo in qualsiasi momento e per qualsiasi ragione trascorsi novanta (90) giorni di calendario previo preavviso scritto. Tale risoluzione non pregiudica gli impegni da entrambe le parti assunti fino alla data di risoluzione, né incide sulla capacità del RICEVENTE di completare qualsiasi impiego nella ricerca del MATERIALE trasferito qui di seguito. // OPPURE Il Presente Accordo terminerà nella prima delle seguenti date: (a) quando il MATERIALE diventi generalmente disponibile per mezzo di terzi, per esempio, tramite cataloghi di reagenti o depositi pubblici o (b) al termine della ricerca corrente del RICEVENTE con il MATERIALE, o (c) con

trenta (30) giorni di preavviso scritto da una delle parti all'altra, o (d) alla data indicata in una lettera di esecuzione, a condizione che: (i) qualora la risoluzione abbia luogo ai sensi dell'Art. 14(a), il RICEVENTE è vincolato al TRASFERENTE dalle condizioni meno restrittive applicabili al MATERIALE ottenuto dalle risorse allora disponibili; e (ii) qualora la risoluzione abbia luogo ai sensi dell'Art. 14(b) o 14(d) sopra menzionati, il RICEVENTE interromperà l'uso del materiale e, su indicazione del TRASFERENTE, restituirà o distruggerà qualsiasi materiale residuo. Il RICEVENTE, a sua discrezione, distruggerà inoltre le MODIFICHE e rimarrà vincolato ai sensi del presente accordo per quanto concerne le MODIFICHE; e (iii) nel caso in cui il TRASFERENTE risolva il presente Accordo ai sensi dell'Art. 14(c) oltre che per violazione del presente Accordo o per giusta causa, come un imminente rischio per la salute o la violazione di un brevetto, il TRASFERENTE rinvierà la data effettiva di risoluzione per un periodo massimo di un anno, su richiesta del RICEVENTE, per consentire il completamento della ricerca in corso. Subito dopo la data effettiva di risoluzione del contratto, o se richiesto, allo scadere del rinvio della stessa, il RICEVENTE interromperà l'uso del materiale e, su indicazione del TRASFERENTE, restituirà o distruggerà qualsiasi materiale residuo. Il RICEVENTE, a sua discrezione, distruggerà inoltre le MODIFICHE e rimarrà vincolato ai sensi del presente accordo per quanto concerne le MODIFICHE.

Il TRASFERENTE e il RICEVENTE devono firmare entrambe le copie della presente lettera e inviare una copia firmata al TRASFERENTE. Il TRASFERENTE invierà quindi il MATERIALE.

DATI e FIRMA AUTORIZZATA DEL TRASFERENTE

Trasferente: Professore

Organizzazione Trasferente Università degli Studi di

Indirizzo: Dipartimento di, Viale

Firma del Trasferente

Data

DATI e FIRMA AUTORIZZATA DEL RICEVENTE

Ricevente:

Organizzazione Ricevente:

Indirizzo:

Firma del Ricevente

Data

Certificazione del Ricevente: Ho letto e compreso le condizioni stabilite nel presente Accordo e acconsento a rispettarle nella ricezione e nell'utilizzo del MATERIALE.

Firma del Ricevente

Data

UniTo MTA

Contratto di trasferimento di material per scopi non commerciali.

Questo Contratto di trasferimento di materiale – di seguito denominato il "Contratto" – è stipulato tra: (1) Università degli Studi di Torino, Dipartimento di Scienze della Vita e Biologia dei Sistemi, con sede legale in via Accademia Albertina, 13, 10123 Torino, rappresentata da ……, in qualità di Direttore del Dipartimento; (in seguito denominato "Fornitore")

E (2) Azienda ……, con sede legale in……, ……,

rappresentata da ……, in qualità di ……; (Di seguito denominato "Ricevente"). Premesso (A) che il Ricevente intende utilizzare per fini non commerciali il materiale elencato nell'Allegato 1, come meglio specificato nell'Allegato 2; (B) che il Fornitore si impegna a fornire tale materiale in conformità alle disposizioni del presente contratto.

Si conviene e si stipula quanto segue.

1. Definizioni

1.1 "Materiale originale" si intende tutto il materiale fornito dal Fornitore al Ricevente, come meglio descritto nell'allegato 1 del presente contratto, che potrà essere modificato previo accordo scritto tra le parti.

1.2 "Progenie" consiste nel materiale discendente non modificato rispetto al material originale, come ad esempio cellule da cellule o organismo da organismo o vettore da vettore.

1.3 "Derivati non modificati" sono sostanze create dal Ricevente che costituiscono una subunità funzionale non modificata o un prodotto derivante dal Materiale originale, ad esempio sottocloni di linee cellulari non modificate, sottoinsiemi purificati o frazionati del Materiale originale, proteine espresse da DNA/RNA.

1.4 "Modifiche" sono sostanze create dal Ricevente che contengono / incorporano il Materiale originale, ad esempio prodotti di ricombinazione omologa, prodotti di scambio di cassette, prodotti di trasmissione di linea germinale, incroci, nuove varietà, fusioni di cellule, prodotti di

subclonazione, ecc.

1.5 "Materiale" si intende (a seconda dei casi) Materiale originale, Progenie, Derivati non modificati inclusi nelle Modifiche.

1.6 "Depositario" è il soggetto che ha fornito il materiale originale al Fornitore.

1.7 "Scambio legittimo" è il trasferimento del Materiale originale all'interno della stessa impresa o ente o gruppo di ricerca (inclusi partners di differenti istituti che collaborano ad un progetto definito).

1.8 "Scopi commerciali" si intende la vendita, locazione, licenza, cessione o altro

trasferimento di materiale ad un soggetto che svolge attività economica con scopo di lucro. L'utilizzo per scopi commerciali è anche quello di qualunque soggetto, compreso il Ricevente, per effettuare ricerca su commissione, comprese la selezione di librerie di composti, per conto di una organizzazione senza scopo di lucro, per produrre o fabbricare I prodotti da vendere, o per

svolgere attività di ricerca che si traducono nella vendita, nella locazione, nella licenza, nel trasferimento del materiale ad una organizzazione a scopo di lucro.

1.9 Gli "Scopi non commerciali" consistono in attività di ricerca, insegnamento o altra attività svolta dal Ricevente senza legami diretti con le attività commerciali quali la vendita, la locazione, la licenza, la cessione o altro trasferimento di materiale ad un soggetto che svolge attività economica con scopo di lucro.

1.10 "Informazioni" includono, senza limitazione, qualsiasi informazione scientifica, tecnica o commerciale, trasmessa al Ricevente da parte del Fornitore nell'ambito del presente contratto.

2. Uso del Materiale

2.1 In esecuzione del presente contratto, il Ricevente si obbliga a pagare le somme di cui al successivo articolo 7 e di prendere in consegna il Materiale originale di cui all'allegato 1. Il Ricevente accetta di ricevere il Materiale originale e di applicare al Materiale le disposizioni che seguono.

2.2 Il Ricevente deve utilizzare il materiale in conformità alle leggi e ai regolamenti, alle line guida e raccomandazioni emesse da organismi internazionali e nazionali applicabili a tale Materiale. In particolare, il Materiale deve essere utilizzato nell'effettivo rispetto delle norme etiche, tenendo conto delle procedure di controllo e delle linee guida etiche adottate dai suddetti organismi internazionali e nazionali. Il Materiale, che è di natura sperimentale, non deve essere utilizzato sull'uomo. Inoltre, il Materiale non deve essere utilizzato sugli animali a meno che - ove applicabile - tale uso sia esplicitamente approvato da un comitato etico o dalla normativa sul trattamento degli animali da laboratorio.

2.3 Il Ricevente dichiara che all'interno dei laboratori (i) l'accesso al Materiale deve essere limitato al solo personale qualificato e in grado di gestire in sicurezza tale Materiale e (ii) che detto Ricevente adotta tutte le misure necessarie, tenendo conto delle caratteristiche specifiche del materiale, di prendere le opportune precauzioni per ridurre al minimo qualsiasi rischio di danno a persone e cose e per proteggerlo dai furti o uso improprio.

2.4 Il Materiale deve essere utilizzato esclusivamente per le attività non commerciali descritte nell'allegato 2.

2.5 Il Materiale non potrà essere trasferito a terzi, senza il preventivo consenso scritto del Fornitore. Allo scopo di evitare ogni dubbio, non potrà essere rifiutato senza motivo il consenso per lo scambio legittimo e per il trasferimento ad un soggetto terzo che agisce senza scopo di lucro. Il terzo dovrà concludere un preventivo con il Fornitore, sostanzialmente uguale al presente.

2.6 Il Ricevente avrà il diritto di richiedere al Fornitore di estendere lo scopo e le attività previste dall'Allegato 2. Il Fornitore non negherà l'autorizzazione in modo irragionevole.

3. **Pubblicazioni**

Il Ricevente ha il diritto di pubblicare i risultati relativi alle attività svolte sul Materiale, a condizione che il Fornitore venga citato come fonte del Materiale. Il Ricevente deve inviare fornire al Fornitore la copia di tutte le pubblicazioni direttamente derivanti dall'utilizzo del Materiale non oltre tre (3) mesi di calendario dalla data della pubblicazione.

4. Proprietà intellettuale

4.1 Tutti i diritti di proprietà intellettuale e tutti i dati, i risultati e le scoperte derivanti dall'uso del materiale è di proprietà del Ricevente, ad eccezione di quanto espressamente previsto nel presente articolo.

4.2 Il Fornitore manterrà la proprietà esclusiva del Materiale originale eventualmente incluso nei risultati derivanti dall'attività di ricerca del Ricevente.

4.3 Il Ricevente ha il diritto di brevettare le invenzioni (incluse le Modifiche) realizzate attraverso l'uso del Materiale ma dovrà comunicare al Fornitore, in modo confidenziale, le rivendicazioni brevettuali delle Modifiche, i metodi di produzione o l'uso del Materiale.

4.4 Qualora il Ricevente depositi un brevetto riguardante una invenzione direttamente derivante dall'uso del Materiale, detto Ricevente dovrà concedere al Fornitore una licenza per tutti i Paesi, gratuita, non esclusiva, che dà diritto a trasferimento e a sublicenze, per la propria attività interna di ricerca e di insegnamento e che permetta al Fornitore medesimo di continuare a distribuire il Materiale a terzi.

4.5 Nel caso in cui il Ricevente intenda sfruttare o utilizzare il Materiale o le Modificazioni per Scopi commerciali deve rivolgere una richiesta formale al Fornitore in modo da ottenere, a discrezione di detto Fornitore, una licenza a titolo oneroso per utilizzare il Materiale o le Modificazioni, secondo gli scopi e le condizioni che verranno stabiliti.

4.6 Previa richiesta del Fornitore, il Ricevente accetta di fornire al Fornitore medesimo una ragionevole quantità di materiali pubblicati realizzati direttamente dal Ricevente a seguito dell'attività di ricerca svolta utilizzando il Materiale. Tali materiali dovranno servire per l'uso interno del Fornitore, per la di ricerca non commerciale e per l'attività didattica. La fornitura di detti materiali dovrà avvenire a titolo gratuito. Potranno essere addebitati soltanto ragionevoli costi di imballaggio e consegna.

4.7 Eccetto per quanto previsto in questo contratto non sono attribuiti al Ricevente altri diritti di proprietà intellettuale o altri diritti di privativa che spettano al Fornitore.

5. Garanzia e responsabilità

5.1 I Materiali forniti nell'ambito del presente contratto si intendono avere carattere sperimentale. Essi possono avere proprietà pericolose.

5.2 Il Ricevente accetta che il Materiale o le Progenie classificati nel Gruppo di Rischio 2 o superiore (come definito dalla normativa dell'Unione europea e quella nazionale) costituiscono patogeni noti e che altro materiale, non così designato possa essere patogeno, in determinate condizioni.

5.3 Il Ricevente accetta che ogni attività di imballaggio e consegna o qualsiasi attività svolta nel proprio laboratorio avvenga in adempimento con ogni legge, regolamento, raccomandazioni e linee guida applicabili.

5.4 Il Ricevente assume ogni responsabilità per danni che potrebbero derivare dall'uso, stoccaggio o smaltimento del Materiale.

5.5 Il Fornitore o il Depositario non si assumono alcuna responsabilità e non garantiscono circa l'idoneità del materiale per un particolare scopo, o che l'uso del materiale non violi alcun brevetto, marchio , o altri diritto di proprietà di un terzo.

5.6 Il Fornitore non avrà alcuna responsabilità nei confronti del Ricevente per eventuali Danni conseguenti (compreso il mancato guadagno), incidentali, indiretti, o per l'applicazione di

sanzioni di ogni tipo derivanti dall'esecuzione del presente contratto o per lo svolgimento di attività riguardanti il Materiale, anche nell'ipotesi in cui il Fornitore è stato avvisato della possibilità di tali danni o conseguenze.

5.7 L'unico rimedio contro il Fornitore (compresi i suoi ausiliari) per eventuali danni di tipo contrattuale ed extracontrattuale, sarà la sostituzione del Materiale.

6. Riservatezza

6.1 Durante la durata del presente accordo e per tre (3) anni successivi, il Ricevente deve mantenere riservate le informazioni e non divulgare tali informazioni a terzi senza il preventive consenso scritto del Fornitore.

7. Costi di imballaggio e consegna

7.1 Il Ricevente si impegna a pagare al Fornitore i costi di spedizione ed eventuali tasse applicabili (ad esempio l'IVA) ai sensi di legge

7.2 Il pagamento è dovuto immediatamente dopo il ricevimento della fattura e deve essere effettuato senza le spese di bonifico sul conto bancario del Fornitore indicato sulla fattura.

7.3 Il Fornitore spedisce il materiale in conformità alle normative di sicurezza internazionali della IATA.

7.4 Dopo la consegna al vettore, la perdita o la distruzione di questo materiale è a rischio del Ricevente.

7.5 Il Ricevente è responsabile di assicurarsi tutti i permessi necessari per ricevere il suo ordine. La prova di tali permessi deve essere fornita al Fornitore, se richiesta.

8. Clausole finali

8.1 Questo contratto sarà interpretato secondo la legge italiana e alle fonti giuridiche dell'Unione europea.

8.2 Il Ricevente deve tenere i libri, registri e altri documenti in modo da fornire ogni ragionevole dettaglio al Fornitore, in modo di verificare l'adempimento delle obbligazione derivanti dal presente contratto. Il Ricevente consentirà inoltre che tali libri, registri documenti siano ispezionati e controllati dauno o più esperti incaricati dal Fornitore.

8.3 Qualsiasi controversia derivante dall'interpretazione e/o esecuzione del presente contratto, che non può essere risolta amichevolmente, verrà decisa dal giudice competente del Foro di Torino.

8.4 Questo contratto entra in vigore alla data della firma apposta e rimane in vigore fino alla conclusione delle attività di cui all'allegato 2 al presente contratto o per il tempo che il destinatario ha il possesso dei Materiali o delle Modifiche, qualunque sia il periodo più lungo.

8.5 Il Ricevente o il Fornitore potranno risolvere dal presente contratto, mediante comunicazione scritta, qualora l'altra parte non pone rimedio, qualora sia possibile, all'inadempimento entro (30) giorni di calendario dal ricevimento della suddetta comunicazione, contente l'indicazione dell'inadempimento da rimediare.

8.6 Le disposizioni del presente contratto relative alla proprietà intellettuale, alla riservatezza, alla responsabilità si applicano anche dopo la fine del presente contratto per qualsiasi motivo.

8.7 Nel caso il Materiale o parte di esso dovesse essere nella detenzione del Ricevente prima della stipula del presente contratto, esso si applicherà con effetto retroattivo.

Firme

Stipulato in duplice copia

Nome e per conto di

Nome e per conto di

Allegato 1. Descrizione del Materiale Originale

Firme

Stipulato in duplice copia

Nome e per conto di

Nome e per conto di

Allegato 2. Descrizione dell'attività da svolgere

Firme

Stipulato in duplice copia

Nome e per conto di

Nome e per conto di

ENGLISH MTAS

Brunswick MTA

MATERIAL TRANSFER AGREEMENT

between

[Insert full name of provider institution], a charitable body registered in [insert jurisdiction of registration] under registration number [insert charitable or royal charter number], incorporated under [insert Act or Charter of Incorporation] and having its main administrative offices at [insert full legal address of provider institution] (the "Provider Institution")

and

[Insert full name of recipient institution], a charitable body registered in [insert jurisdiction of registration] under registration number [insert charitable or royal charter number], incorporated under [insert Act or Charter of Incorporation] and having its main administrative offices at [insert full legal address of recipient institution] ("Recipient Institution")

hereinafter referred to as "the Parties" and each of them being "a Party"

BACKGROUND

(A) The Recipient Institution is conducting a research project entitled "[insert title of research project]" as described in more detail at Appendix 1 ("the Research") under the direction of [insert name of Principal Investigator] ("the Recipient Scientist") and wishes to access and utilise the material identified in Appendix 2 (the "Material") for the purpose of the Research. The term "Material" includes but is not limited to material, other than human gametes or embryos, which consists of, or includes human cells and which is considered "Relevant Material" for the purposes of the Human Tissue Act 2004[1057] together with related data.

(B) The Provider Institution is willing to supply the Material to the Recipient Institution and the Recipient is willing to receive the Material in accordance with the terms and conditions contained within this agreement (the "Agreement");

TERMS AND CONDITIONS

1. The Recipient Institution will hold the Material on the terms of this Agreement and solely for the purpose of the Research within the research group of the Recipient Scientist.

2. The Recipient Institution hereby agrees to comply and procure that the Recipient Scientist and all personnel who work with the Material comply with the terms and conditions of this Agreement. The Recipient Institution will not use the Material for (a) administration to human subjects or (b) "human application" as that term is defined in the Human Tissue

[1057] The Human Tissue Act 2004 applies to the "authorised activities" principally the removal, storage and use of "Relevant Materials" (as defined under the Act, including human cells, tissue and organs, but not cell lines) which come from a living or deceased person for "Scheduled Purposes" (these are set out in Schedule 1 of the Act, including, but not limited to, "research in connection with disorders, or the function of the human body", "education or training relating to human health", and "transplantation").

(Quality and Safety for Human Application) Regulations 2007 (or equivalent as may be replaced or amended from time to time), or for clinical or diagnostic purposes.[1058]

3. The Recipient Institution may use the Material for the purposes of the Research and as described in Appendix 1, from the date of receipt of the Material until [insert date][the conclusion of the Research]. With respect to its use of the Material (including, not limited to disposal or return), the Recipient Institution will comply fully with all applicable environmental, health and safety laws, and other applicable laws which means all laws, rules, regulations, codes of practice, research governance or ethical guidelines, or other requirements of any regulatory authority, that may apply to the use of the Material by the Recipient Institution from time to time, including (but not limited to) the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as applicable), the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the Human Fertilisation and Embryology Act 1990 (as amended), the EU Tissues and Cells Directive (2004/23/EC) and Commission Directives 2006/17/EC and 2006/86/EC, The Human Tissue Authority Directions and Codes of Practice, and the Medicines for Human Use (Clinical Trials) Regulations 2004, as updated and amended from time to time and, where relevant, the national implementations of the same ("Applicable Laws").

4. The Recipient Institution shall use a courier with suitable skill and experience to safely transport the Material in accordance with all Applicable Laws. The Recipient Institution will bear the cost of carriage and any necessary insurance. [The Provider Institution makes no charge for the Material.] [The Material is provided subject to the reimbursement by the Recipient Institution to the Provider Institution for its costs of extracting from storage and preparing the Material as set out in Appendix 2.] Risk in and responsibility for the Material shall pass to the Recipient Institution once it is loaded onto transport as organised by the Recipient Institution. If so requested by the Provider Institution the Recipient Institution shall provide it with written confirmation of the safe receipt of the Materials promptly after their delivery to the Recipient Institution's laboratory.

5. The Recipient Institution understands that the Material may have hazardous properties, contain infectious agents or pose other health and safety risks. Subject to clause 10, the Provider Institution makes no representations and gives no warranties either express or implied in relation to it: for example (without limitation), no warranties are given about quality or fitness for a particular purpose, or freedom from infection. The Provider Institution will not be liable for any use made of the Material by the Recipient Institution. The Recipient Institution will use the Material in accordance with good laboratory practice standards, all due skill and care and with dignity, sensitivity and respect. The Recipient Institution will comply with all Applicable Laws, approvals, rules, codes of practice and regulations governing the transportation, storage, use and disposal of the Material. The Recipient Institution warrants that it will only use, or permit the use of the Material in work that has ethical approval, as stated in Appendix 1.

6. Except to the extent prohibited by law and subject to clause 10, the Recipient Institution assumes all liability for damages which may arise from its receipt, use, storage or disposal of the Material. The Provider Institution will not be liable to the Recipient Institution for any loss, claim or demand made by the Recipient Institution, or made against the Recipient Institution by any other party, due to or arising from its use, storage or disposal of the Material by the Recipient Institution, except to the extent the law otherwise requires.

[1058] The Human Tissue (Quality and Safety for Human Application) Regulations 2007 apply to the procurement, testing, processing, storage, distribution, and import or export of tissues and cells (including cell lines). "Cells" mean human cells (whether individually or in an unbound collection) including cell lines, but not including gametes, embryos outside the body, blood or blood components. "Tissue" for the Regulations, means all constituent parts of the human body formed by cells, but not including gametes and embryos outside the body (which are regulated by the Human Fertilisation and Embryology Authority pursuant to the Human Fertilisation and Embryology Act 1990), or organs.

7. The liability of either Party for any breach of this Agreement, or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.

8. The Recipient Institution agrees to obtain the written consent of the Provider Institution if there is any material change to the proposed use of the Material in the Research as described in Appendix 1.

9. The Material is provided and the Research is undertaken in pursuit of the primary charitable objectives of the Parties; that is the advancement of education through research and teaching. The Provider Institution acknowledges that the results of the Research shall belong to the Recipient Institution (except that the Provider Institution retains ownership rights to any Material included therein), and that the Recipient Institution may seek to publish the results of the Research. The Recipient Institution shall procure that in relation to any publication reporting on the use of the Material, the Recipient Scientist acknowledges the Provider Institution as the source of the Material within it and, where the Provider Institution requests, provides a copy of such publication to the Provider Institution thirty days in advance of submission for publication. The Provider Institution agrees not to share such advance copy with any third party until published by the Recipient Institution. The Recipient Institution shall not publish any confidential or proprietary information belonging to the Provider Institution without its prior written consent, including such information contained within the Material provided. Confidential and proprietary information shall be deemed to include information which was described as such at the point of disclosure and/or was marked as either "confidential" or "proprietary". The confidentiality obligations in this clause shall not apply where the confidential or proprietary information:

   (a) has become public knowledge, other than through an unauthorised disclosure by the Recipient Institution;

   (b) was already known to the Recipient Institution, prior to disclosure by the Provider Institution;

   (c) was disclosed to the Recipient Institution or the Recipient Scientist by a third party, whom to the Recipient Institution's knowledge, was not under any obligation of confidence to the Provider Institution;

   (d) was released from confidential status by written authorisation of the Provider Institution; or

   (e) is required to be disclosed by law or by requirement of a regulatory body or court order.

10. The Provider Institution warrants that where required by Applicable Laws the Material has been obtained from humans with the appropriate consent as required by the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as applicable) and with ethical approval and the Provider Institution shall be liable for any claims arising due to the breach of this warranty. The Provider Institution hereby grants to the Recipient Institution a non-exclusive research licence to use the Material for the Research only. The Provider Institution further warrants that it has not provided any information (and does not intend to provide any information) which has led or may lead to the Recipient Institution being able to identify the person from whom the relevant material came.

11. The Recipient Institution undertakes to store the Material in accordance with all Applicable Laws and not to attempt to identify or contact the donor of the Material or to compromise or otherwise infringe the confidentiality of information on the donors and their right to privacy.

12. Nothing included in this Agreement shall prevent the Provider Institution from being able to distribute the Material to other entities as described in Appendix 1. If, as per the details included in Appendix 1, the Material is to be transferred to another institution for the purposes of the Research, the responsibility for compliance with the terms of this Agreement rests with the Recipient Institution.

13. The Provider Institution has the right to terminate this agreement forthwith at any time by means of written notice to Recipient Institution if the ethical approval is withdrawn or if the Recipient Institution is in breach of this Agreement. In the case of any termination, the Recipient Institution shall immediately discontinue all use of the Material and, at the Provider Institution's discretion, promptly return or destroy (at the Recipient Institution's own cost) all unused Material and provide written confirmation that this has been completed. If requested, the Recipient Institution must certify that it has complied in full with any such requirement of the Provider Institution. Should an individual donor or their next of kin rescind their consent, the Provider Institution will require and the Recipient Institution agrees to discontinue using the appropriately identified sample and return or destroy it in accordance with the Provider Institution's instructions.

14. This Agreement shall be governed and construed in accordance with the laws of [England and Wales] [Scotland] [Northern Ireland] and the Parties agree to the exclusive jurisdiction of the [English] [Scottish] Courts [of Northern Ireland].

Accepted and Agreed by an authorised signatory on behalf of	Accepted and Agreed on behalf of
[insert full legal name of Recipient Institution]	[insert full legal name of Provider Institution]
Name:	Name:
Position:	Position:
Signature	Signature:
Date:	Date:

Bristol MTA

MATERIAL TRANSFER AGREEMENT

THIS AGREEMENT is made the ___ day of _____ 20__ between

THE UNIVERSITY OF BRISTOL of Senate House, Tyndall Avenue, Bristol BS8 1TH, ("the University"), acting through the AVON LONGITUDINAL STUDY OF PARENTS AND CHILDREN of the School of Social and Community Medicine, Oakfield House, Oakfield Grove, Clifton, Bristol BS8 2BN ("ALSPAC"),

and …… of …….. (referred to as "the Recipient")

Hereafter referred to collectively as "Parties" and individually as "Party".

BACKGROUND:

The University, through ALSPAC, has collected and owns certain biological research material provided by participants in the Avon Longitudinal Study of Parents and Children ("Study Participants"). An employee of the Recipient, named in the Appendix ("Investigator"), wishes to use certain of the material held by ALSPAC ("the Material") as set out in the Appendix . The Material is to be used by the Recipient in the research described in the Appendix ("the Research") and agreed by the ALSPAC Executive Committee. ALSPAC is willing to supply the Recipient with the Material for a period of one year to conduct the Research under the terms and conditions of this Agreement.

NOW IT IS AGREED by the Parties as follows:

1. That the Investigator and other relevant employees of the Recipient involved in the Research have read and will abide by the "ALSPAC Collaboration Policy" at http://www.bristol.ac.uk/alspac/researchers/access/. All future correspondence pertaining to the Material and the Research should be addressed to ALSPAC.

2. The Material remains the property of the University. There is no transfer or licence or implied transfer or licence of rights in the Material from the University to the Recipient including all intellectual property rights. This Agreement does not restrict the rights of ALSPAC to distribute the Material to other institutions or to publish any document relating to the Material.

3. The Recipient will use the Material in accordance with good laboratory practice and shall ensure compliance with all applicable laws, regulations and research governance pertaining to the Research.

4. The Recipient will retain the Material in a secure location on its premises and will not permit the Material or any part of it to come into the possession or control of any other organisation or any individual other than those employees who are involved in the Research described in the Appendix under direct supervision of the Recipient. The Recipient will ensure that suitable systems are in place for the tracking of Material while in its possession. The Recipient will not transfer the Material in whole or in part to third parties without the relevant third party entering into a separate Material Transfer Agreement with ALSPAC.

5. The Recipient will use the Material only to carry out the Research described in the Appendix to this Agreement, and only for Research that has appropriate ethical approval. The Recipient will not use the Material or any parts thereof for any commercial purpose or any purpose that is subject to consulting or licensing obligations to third parties.

6. The Recipient will not use the Material in any experiments involving humans and will not use the Material in contact with any cells or other materials to be infused into humans. If animal studies have been proposed, Investigator has considered *in vitro* approaches to the research and has followed the applicable guidelines for animal experimentation regarding such work.

7. The Recipient will use all reasonable endeavours to ensure that the Material in its possession or under the control of the Recipient as soon as possible be returned or destroyed upon (i) the reasonable request of ALSPAC; or (ii) on termination of this agreement; or (iii) in the event that either Party is in breach of any of the conditions of this Agreement; or (iv) the consent of the relevant Study Participant is withdrawn. If the Recipient is required to destroy the Materials then it will ensure that this is done in compliance with all applicable laws and regulations and will confirm in writing to ALSPAC that the Materials have been destroyed.

8. The Recipient will keep ALSPAC informed of the results of the Research ("Results") every 6 months. The University will own all Results directly relating to the Study Participants for the purposes of incorporation into ALSPAC. All other results generated by the Research shall be the property of the Recipient save that the Recipient grants to the University a royalty-free, irrevocable, perpetual non-exclusive right to use such Results for internal non-commercial research and teaching. The Recipient will provide ALSPAC with a fully documented electronic copy of the Results before publication in any form or within 6 months of the completion of the Research whichever is the sooner.

9. The Recipient will acknowledge ALSPAC and include as authors those University employees identified by the ALSPAC Executive Committee who have played a key scientific role in the generation of the Material in all publications relating to the Research and Results. The ALSPAC Executive Committee will be given the opportunity to review any papers intended for publication at least 14 days prior to submission.

10. The Recipient will keep the Materials and any data provided by ALSPAC confidential and will not try to identify Study Participants.

11. The Recipient will not try to link any data provided by ALSPAC to other ALSPAC data held by different recipients or by the same Recipient for different projects.

12. The Materials are supplied without cost but the Recipient shall reimburse ALSPAC for any reasonable costs that may be incurred when preparing and sending the Materials to the Recipient.

13. ALSPAC accepts no liabilitiy in connection with the Recipients use of the Material. ALSPAC does not represent that (i) the Materials are of satisfactory quality or fit for any particular purpose; or (ii) use of the Material is free from infringement of third party rights, including intellectual property rights. To the extent permisable by law the Recipient will indemnify and hold the University harmless for any damages howsoever arising from Recipient's use of the Material.

14. The Recipient will neither assign, transfer, mortgage, charge nor part with any of its interests, rights, duties or obligations under this Agreement.

15. This Agreement will be governed by the laws of England and shall be subject to the jurisdiction of the English Courts. This clause shall not prevent a party from seeking interim relief in any court of competent jurisdiction.

AGREED BY THE PARTIES through their authorised signatories

SIGNED for and on behalf of THE UNIVERSITY OF BRISTOL:

Name: ……..

Date: ……

SIGNED for and on behalf of RECIPIENT:

(1) Authorised signatory of Recipient ……

Name: ……

Date: ……

(2) Signature of Investigator: ……..

Name: ……..

Date: ……

UCL MTA

SUPPLY AGREEMENT FOR THE PROVISION OF HUMAN TISSUE SAMPLES AND TISSUE DONOR INFORMATI0N WITHIN UNIVERSITY COLLEGE LONDON FOR RESEARCH PURPOSES ONLY (IoN HTA)

BETWEEN:

Name, Department and address of the Principal Researcher ("RECIPIENT")

and

University College London, Gower Street, London WC1E 6BT. ("PROVIDER")

WHEREAS

A. This Material Transfer Agreement (MTA; "Agreement") contains the terms and conditions under which the PROVIDER, acting through the UCL Institute of Neurology, 23 Queen Square, London, WC1N 3BG, has agreed to provide the RECIPIENT with human tissue samples consisting of or including whole cells, namely post-mortem tissue, surplus biopsy or surgical tissue, non-transplantable tissue, body fluids, primary cell cultures (whole explant/biopsy present) or microdissected cells as detailed in Appendix A and hereinafter referred to as "TISSUE".

B. The TISSUE is for use only in the research project as described in Appendix A ("RESEARCH PROJECT") to be undertaken by [**INSERT NAME]** (the "PRINCIPAL RESEARCHER") who is an employee of University College London (UCL). If the PRINCIPAL RESEARCHER is replaced the RECIPIENT will provide the name of the replacement PRINCIPAL RESEARCHER to the PROVIDER.

C. The PROVIDER'S Tissue Bank MTA Approval Committee must approve the RESEARCH PROJECT. Research Tissue Banks (RTBs) are authorized by a NHS Research Ethics Committee (REC) to give generic ethical approval, but Standard Tissue Banks do not give generic ethical approval. If the Tissue Bank is a RTB the RECIPIENT may request in Appendix A that generic ethical approval is given for the RESEARCH PROJECT if conducted in the U.K.. This project-specific generic ethical approval will not be valid when this Agreement expires or is terminated. Where generic ethical approval is not given, the RECIPIENT'S NHS REC approval letter(s) for the RESEARCH PROJECT must be attached at Appendix E.

D. The term "TISSUE" means human material (excluding gametes, embryos, or cells that have divided in culture) which consists of or includes human cells and so is considered to be "Relevant Material" for the purposes of the Human Tissue Act 2004 and the Human Tissue Authority (HTA). TISSUE would be provided by the PROVIDER together with related basic information (including age, sex, previous and current diseases, and drug history) of tissue donors ("DONOR INFORMATION"). The RECIPIENT will hold the TISSUE and DONOR INFORMATION on the terms of this Agreement and solely for the purpose of the RESEARCH PROJECT as described in Appendix A within the research group of the PRINCIPAL RESEARCHER.

IT IS HEREBY AGREED AS FOLLOWS

1. The PROVIDER represents and warrants that the consent obtained for TISSUE donation, and the procurement and storage of TISSUE and the DONOR INFORMATION, for research studies are in accordance with the Human Tissue Act 2004, the HTA Codes of Practice, the PROVIDER'S relevant NHS Research Ethics Committee (REC) approval(s), and other relevant laws and guidelines. The UCL Institute of Neurology has been granted the HTA Licence Number 12198 in the Research Sector. A copy of the PROVIDER'S Research Ethics Committee approval(s) which is relevant to the TISSUE and DONOR INFORMATION supplied is attached at Appendix B.

2. The TISSUE and DONOR INFORMATION supplied to the RECIPIENT have been obtained from living donors for whom written informed consent was given by the donor, next of kin or person with power of attorney for the donor's TISSUE and DONOR INFORMATION to be used for research purposes, and/or for whom written informed consent was given after the death of the donor by their next of kin or person with power of attorney. Sample copies of the current Tissue Bank, Laboratory or Hospital Consent Form(s) used by the PROVIDER are attached to this Agreement at Appendix C. Should an individual donor, or donor's next of kin, rescind consent the PROVIDER will notify the RECIPIENT and the RECIPIENT will agree to discontinue use of the TISSUE and return any remaining TISSUE concerned to the PROVIDER in accordance with the PROVIDER'S instructions.

3. The PROVIDER warrants to the RECIPIENT that no payments were made or other inducements given to any donor or next of kin or other consenting person to procure the TISSUE or DONOR INFORMATION.

4. The RECIPIENT hereby agrees to comply, and procure that the PRINCIPAL RESEARCHER and all personnel who work with the TISSUE and DONOR INFORMATION comply with the terms and conditions in this Agreement. Where TISSUE under the RESEARCH PROJECT is outsourced to a third party for experimental work that cannot be carried out in the RECIPIENT'S Laboratories, the RECIPIENT shall ensure that relevant terms and conditions of this Agreement are formally agreed by the third party through a Third Party Agreement (TPA) between University College London and the third party. The RESEARCH PROJECT may include RNA analysis and gene expression studies in line with the donor consent and the Codes of Practice of the Human Tissue Authority. All TISSUE is for research purposes only and the RECIPIENT will not use the TISSUE for Human Application (i.e. patient treatment) as that term is defined in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (or equivalent as may be replaced or amended from time to time), or for clinical or diagnostic purposes.

5. The RECIPIENT will make appropriate payment to cover reasonable administration costs for the storage and supply and preparation of the TISSUE and DONOR INFORMATION but the RECIPIENT shall make no payment for the TISSUE samples or DONOR INFORMATION. All costs for the TISSUE and DONOR INFORMATION will be agreed between the PROVIDER and the RECIPIENT prior to any transfer of the TISSUE and DONOR INFORMATION. No payment will be made to the PROVIDER by the RECIPIENT in respect of any invention or discovery arising from the use of the TISSUE and DONOR INFORMATION. The RECIPIENT shall own the results of the research and resulting intellectual property rights arising from the RECIPIENT'S use of the TISSUE and DONOR INFORMATION.

6. TISSUE will be anonymised by coding and supplied when appropriate with basic DONOR INFORMATION. Under no circumstances shall the PROVIDER supply or shall RECIPIENT accept personal information which in the PROVIDER'S opinion could identify the donor.

7. Upon the RECIPIENT'S request, the PROVIDER shall provide the RECIPIENT with technical information necessary for the safe handling, storage and use of the TISSUE. The PROVIDER will retain for reference any tissue sections which have been stained by the PROVIDER to characterize TISSUE passed to the RECIPIENT.

8. The PROVIDER will arrange for and the RECIPIENT will cover the costs for all transport of the TISSUE. The RECIPIENT will supply the PROVIDER with, or pay the PROVIDER for, all slides, tubes, containers, packaging and labelling as required by the PROVIDER to provide the RECIPIENT with the TISSUE. To minimize the possibility of damage or loss, the required packaging must be robust and clearly labelled with the RECIPIENT'S name, address and contact details. Prior to sample transport to the RECIPIENT, the PROVIDER will e-mail the RECIPIENT the "Dispatch and Confirmation of Receipt Form" attached to this Agreement at Appendix D. Also in advance of transportation the PROVIDER must give the courier company or the individual who would be transporting the samples detailed information on how the samples are to be preserved during transport, including maintenance of the correct temperature, and on any potential biological (e.g. infection), chemical (e.g. formalin) or other hazards (e.g. transport in dry ice).

9. The courier must endeavour to prevent damage, loss or theft of the transported TISSUE. It must be ensured by the courier that the transport containers are held in place securely to prevent them moving during transport, and that the specified optimal temperature conditions are maintained throughout all stages of the delivery process. The vehicle transport compartment must be windowless and kept locked until delivery to the RECIPIENT. To acknowledge the safe receipt of TISSUE, the RECIPIENT must as soon as possible send by e-mail or fax the completed "Dispatch and Confirmation of Receipt Form" to the PROVIDER. The storage conditions for preservation of the TISSUE SAMPLES by the RECIPIENT and any associated hazards are specified on this Form. If TISSUE is transported by a courier company RECIPIENT must also send a copy of the courier company's signed delivery Form to the PROVIDER. The risk and responsibility (i.e. custodianship) for the TISSUE shall pass to the RECIPIENT when the courier company's delivery form has been signed at the RECIPIENT'S institution, or the RECIPIENT has collected the TISSUE from the PROVIDER.

10. On receiving custodianship of the TISSUE and DONOR INFORMATION, the RECIPIENT will then be responsible for the appropriate storage and use of the TISSUE and the DONOR INFORMATION. The RECIPIENT may use the TISSUE and DONOR INFORMATION only in the RESEARCH PROJECT, and in accordance with the RECIPIENT'S Research Ethics Committee approval(s) if attached at Appendix E. The RECIPIENT agrees to obtain the written consent of the PROVIDER if there is any material change to the proposed use of the TISSUE and DONOR INFORMATION. The RECIPIENT may pass the TISSUE and DONOR INFORMATION on to its employees solely for performance of the RESEARCH PROJECT but may not sell, licence or otherwise transfer the TISSUE or DONOR INFORMATION to any third party, other than as permitted in this Agreement for the purpose of the outsourcing of experimental work, without prior written consent from the PROVIDER.

11. Both Parties shall keep confidential all details of this Agreement and information relating to this Agreement unless prior written agreement is obtained in advance of any disclosure. This obligation of confidentiality shall survive termination of this Agreement indefinitely. The obligations of confidentiality shall not apply to any information (i) that the receiving party can show was known to the receiving party in advance of receipt from the disclosing party; (ii) is in the public domain or subsequently becomes publicly known through no fault, act or omission of the receiving party; (iii) is received by the receiving party without restriction from a third party lawfully entitled to make the disclosure to the receiving party without any such restriction; (iv) is developed by the receiving party independently and without the aid or benefit of the information obtained from the disclosing party; (v) the receiving party is required to disclose by law, government regulation or court order provided the receiving party notifies the disclosing party of such requirement in advance of disclosure.

12. Each Party shall ensure that its activity under this Agreement shall comply fully with applicable laws and guidance including but not limited to the current Codes of Practice of the Human Tissue Authority and all other relevant local, government and European Laws, regulations and guidelines which are applicable during the period of this Agreement, including health and safety, data protection and environmental laws with regard to the TISSUE and DONOR INFORMATION.

13. To comply with safety legislation, the RECIPIENT is required to carry out formal Risk Assessments and produce Standard Operating Procedures for all research work involving the TISSUE and DONOR INFORMATION**.** The RECIPIENT warrants to assume full responsibility for training all personnel in procedures for the safe handling of human tissues. The PROVIDER warrants to have taken all reasonable precautions in supplying the TISSUE to the RECIPIENT and accepts no liability for any potential risks associated with the RECIPIENT'S use of the TISSUE. Except as expressly stated herein, the RECIPIENT acknowledges that the TISSUE is experimental in nature and the PROVIDER makes no representation and gives no warranty or undertaking of quality or fitness of the TISSUE or DONOR INFORMATION for any particular purpose or that their use will not infringe any patent, copyright, trade mark or other property right owned by any third party.

14. The RECIPIENT will provide the PROVIDER with an Annual Report and the Final Report on the RESEARCH PROJECT described in Appendix A, to be held in confidence by the PROVIDER.

15. The PRINCIPAL RESEARCHER agrees to provide appropriate acknowledgement of the Tissue Bank as the source of the TISSUE and/or DONOR INFORMATION in all written publications or oral presentations reporting on the use of the TISSUE and/or DONOR INFORMATION. The PRINCIPAL RESEARCHER will provide a copy of such publications at least twenty days in advance of submission for publication. The PROVIDER agrees not to share such advance copy with any third party until published. The RECIPIENT shall not publish any confidential or proprietary information belonging to the PROVIDER without its prior written consent, including such information contained within the TISSUE and DONOR INFORMATION. At any time the PRINCIPAL RESEARCHER and Tissue Bank representative(s) may agree that collaborating with each other in the performance of this RESEARCH PROJECT will be of mutual benefit, further research objectives and foster the development of scientific knowledge. If this has been agreed the Tissue Bank representative(s) will be included in any publication as co-author(s), unless requested otherwise by a Tissue Bank representative. These obligations shall survive termination of this Agreement indefinitely.

16. Unused tissue must be returned when this Agreement expires, or the RECIPIENT notifies the PROVIDER that the RESEARCH PROJECT is completed or terminated, or if any remaining TISSUE is no longer required, or if the RECIPIENT'S non-generic Research Ethics Committee approval(s) attached at Appendix E expires, whichever is the sooner. Samples which have been homogenized or rendered acellular by other means should be disposed of by the RECIPIENT under the regulations of their establishment. However samples containing whole cells, or tissue sections on slides or in tubes, must be returned to the PROVIDER for disposal in a lawful and respectful manner in compliance with the Human Tissue Act 2004, HTA Codes and UCL Policies. The RECIPIENT must document in detail and return all unused TISSUE to the PROVIDER in appropriately labelled containers and packaging unless a new Agreement is approved by the PROVIDER, and/or new Research Ethics Committee approval is obtained. A copy of any non-generic new approval by the RECIPIENT'S Research Ethics Committee must be sent to the PROVIDER within 30 (thirty) days of notification of such approval.

17. This Agreement shall take effect from [**insert date, 201x**], and shall be for a maximum period of [**insert number**] years, **expiring on [insert date, 20xx].** The RECIPIENT may wish to request small amounts of additional samples from the PROVIDER, and/or tovmake minor changes to the methodologies included in Appendix A ("RESEARCH PROJECT") by utilizing a UCL Institute of Neurology Amendment document. This Agreement would be modified only to the extent expressly stated in the Amendment. All other provisions specified in the Agreement would remain unchanged and in full force and effect, including the expiry of the Amendment, Agreement and any generic ethical approval on the date stated in the original Agreement**.** In the event of breach of this Agreement, or any Amendment to this Agreement, by the RECIPIENT and following failure to remedy such breach within 30 days, the PROVIDER may terminate the Agreement on 30 days written notice being given to the RECIPIENT.

18. Official notices shall be in writing and may be given by hand or sent by first class post, as a PDF e-mail attachment, or facsimile addressed to the signatories of this Agreement. If delivered by hand, service shall be deemed to have been given upon delivery. If sent by post, service shall be deemed to have been given 48 hours after posting, and if sent electronically as a PDF attachment or facsimile shall be deemed to have been given on the date of transmission provided that a successful transmission report is held by the sender and a copy of the PDF attachment or facsimile and the transmission report is sent by post to the RECIPIENT. Informal comments and concerns may be made in writing by either party by post, e-mail or facsimile to the relevant Tissue Bank or Laboratory Manager, contact details for whom are given in Appendix A.

Lambert MTA

THIS AGREEMENT dated [……..] 20[ ] is made **BETWEEN:**

(1) **[……..]**, whose administrative offices are at [……] (the University);

(2) **[……..]** [**LIMITED**], a company registered in [England] under number [……], whose registered office is at [……] (the Company)

1. **DEFINITIONS**

In this Agreement the following expressions have the meaning set opposite:

Academic Publication:	the publication of an abstract, article or paper in a journal, or its presentation at a conference or seminar; and in clauses 5 and 6 "to Publish" and "Publication" are to be construed as references to Academic Publication;
this Agreement:	this document including its Schedule, as amended from time to time in accordance with clause 9.9;
a Business Day:	Monday to Friday (inclusive) except bank or public holidays in [England];
Confidential Information:	in the case of the Company, the Materials and in the case of the University, the Results, the Improvements and the Project;
the Field:	[*insert business area*];
a Group Company:	any undertaking which is, on or after the date of this Agreement from time to time, a subsidiary undertaking of the Company, a parent undertaking of the Company or a subsidiary undertaking of a parent undertaking of the Company, as those terms are defined in section 258 of the

	Companies Act 1985;
Intellectual Property:	patents, trade marks, service marks, registered designs, copyrights, database rights, design rights, confidential information, applications for any of the above, and any similar right recognised from time to time in any jurisdiction, together with all rights of action in relation to the infringement of any of the above;
Know-how:	unpatented technical information (including, without limitation information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, techniques and specifications, quality control data, analyses, reports and submissions) that is not in the public domain;
an Improvement:	a material enhancement to the functionality of any of the Materials created in the course of the Project, except a new use discovered for any of the Materials;
the Materials:	the materials described in Part A of the Schedule[, including any construct, strain, replication, progeny or derivative that contains any of the Materials,] and all Know-how supplied by the Company to the University relating to any of the Materials;
[the Price:	[£[*insert amount*] sterling;]
the Principal Investigator:	[*insert name*];
the Project:	the [academic] OR [non-clinical] research project(s) described in Part B of the Schedule;
the Results:	all information, Know-how, results, inventions, software and other Intellectual Property (except an Improvement) identified or first reduced to practice or writing as a result of using the Materials in the Project;
the Term:	[*insert figure*] [months][years] beginning on the date of this Agreement, or the end of the Project (whichever is earlier); and

the Territory: [worldwide] OR [*insert geographical area*].

TERMS AND CONDITIONS FOR USE

2.1 The Company will provide the Materials to the University on the terms and conditions of this Agreement.

2.2 The University will use the Materials only for the Project [and only as specified in the PI's request to the Company for the Materials], and not for any commercial purpose or commercially-sponsored research (even if these activities are being pursued in the University's laboratory) without first obtaining the Company's written consent.

2.3 The University will not supply the Materials to any person, except the Principal Investigator and people under the Principal Investigator's direct supervision, or allow them to be removed from the University's premises unless it first obtains the Company's written consent.

2.4 The University will use the Materials in accordance with all applicable laws, regulations, and governmental guidelines.

2.5 The University will provide the Company with [[monthly][annual][quarterly] reports summarising the progress of the use of the Materials in the Project and][a final report within [3]months after the completion of the use of the Materials in the Project] and a copy of all of the Results and Improvements.

2.6 The Term may be extended only by the written agreement of the Company and the University.

3. **PAYMENT**

[The University will pay the Company the Price in full on the date of this Agreement. All amounts payable to the Company under this Agreement are exclusive of VAT (or any similar tax) which the University will pay at the rate from time to time prescribed by law.]

OR

[The Materials are provided to the University free of charge.]

4. **USE AND EXPLOITATION OF INTELLECTUAL PROPERTY**

4.1 No licence under any Intellectual Property owned or controlled by the Company is granted or implied by this Agreement other than the right for the University to have possession of, and use, the Materials in accordance with the terms of this Agreement.

4.2 The University will own the Intellectual Property in the Results, and may take such steps as it may decide from time to time, and at its own expense, to register and maintain any protection for that Intellectual Property, including filing and prosecuting patent applications for any of the Results.

4.3 The Company will own the Intellectual Property in the Improvements and may take such steps as it may decide from time to time, and at its own expense, to register and maintain any protection for that Intellectual Property, including filing and prosecuting patent applications for any of the Improvements.

4.4 Where any third party such as a student or contractor is involved in the Project, the University or the party engaging that contractor (as the case may be) will ensure that that student and that contractor assign any Intellectual Property they may have in the Results and in the Improvements in order to be able to give effect to the provisions of this clause 4.

4.5 To the extent that any Intellectual Property in the Improvements is capable of prospective assignment, the University now assigns that Intellectual Property to the Sponsor; and to the extent any Intellectual Property in the Improvements cannot prospectively be assigned, the University will assign that Intellectual Property to the Company as and when it is created, at the request of the Company.

4.6 The University will notify the Company promptly after identifying any Result or any Improvement that the University believes is patentable, and will supply the Company with copies of that Result or Improvement as the case may be. The University will notify other Results and Improvements to the Company in the reports provided under clause 2.5.

4.7 The University grants to the Company a non-exclusive, indefinite [fully paid-up, royalty free] licence (with the right to sub-license to any Group Company and to any person working for, or on behalf of, the Company or any Group Company, but only for the purpose of carrying out that work, and otherwise without the right to sub-license) to use the Intellectual Property in any of the Results for any purpose within the Field in the Territory.

4.8 The Company grants the University a royalty-free, non-exclusive licence to use the Improvements for the purpose of carrying out the Project, but for no other purpose. The University may not grant any sub-licence to use the Improvements.

4.9 Despite the assignment or agreement to assign under clause 4.5, the University and each employee and student of the University will have the irrevocable, royalty-free right to use the Improvements for the purposes of academic teaching and academic research[and clinical patient care][, including research projects that are sponsored by any third party]. The rights in this clause are subject to the rules on Academic Publication in clause 5.

5. ACADEMIC PUBLICATION

5.1 The Project is undertaken in pursuance of a primary charitable purpose of the University; that is the advancement of education through teaching and research. Therefore, any employee or student of the University (whether or not involved in the Project) may, provided the University has not received a Confidentiality Notice under clause 5.2:

5.1.1 discuss work undertaken as part of the Project in University seminars, tutorials and lectures; and

5.1.2 Publish any of the Results and any of the Improvements.

5.2 The University will submit to the Company, in writing, details of any Results or Improvements that any employee or student of the University intends to Publish, at least [30][60] days before the date of the proposed Publication. The Company may, by giving written notice to the University (a Confidentiality Notice) require the University to delay the proposed Publication for a maximum of [3] months after receipt of the Confidentiality Notice if, in the Company's reasonable opinion, that delay is necessary in order to seek patent or similar protection for any of the Results or Improvements that are to be Published. The Company must give that Confidentiality Notice within [15][30]

days after the Company receives details of the proposed Publication. If the University does not receive a Confidentiality Notice within that period, its employee or student may proceed with the proposed Publication.

6. **CONFIDENTIALITY**

6.1 Subject to clause 5, neither party will[, either during the Term or for [3][5][7][10] years after the end of the Term,] disclose to any third party, nor use for any purpose except as expressly permitted by this Agreement, any of the other party's Confidential Information.

6.2 Neither party will be in breach of any obligation to keep any information confidential or not to disclose it to any other party to the extent that it:

6.2.1 is known to the party making the disclosure before its receipt from the other party, and not already subject to any obligation of confidentiality to the other party;

6.2.2 is or becomes publicly known without any breach of this Agreement or any other undertaking to keep it confidential;

6.2.3 has been obtained by the party making the disclosure from a third party in circumstances where the party making the disclosure has no reason to believe that there has been a breach of an obligation of confidentiality owed to the other party;

6.2.4 has been independently developed by the party making the disclosure;

6.2.5 is disclosed pursuant to the requirement of any law or regulation (provided, in the case of a disclosure under the Freedom of Information Act 2000, none of the exceptions to that Act applies to the information disclosed) or the order of any Court of competent jurisdiction, and the party required to make that disclosure has informed the other, within a reasonable time after being required to make the disclosure, of the requirement to disclose and the information required to be disclosed; or

6.2.6 is approved for release in writing by an authorised representative of the other party.

6.3 The University will not be in breach of any obligation to keep any information confidential, or not to disclose it to any third party, by Publishing any of the same if the University has followed the procedure in clause 5.2 and has received no Confidentiality Notice within the period stated in that clause.

6.4 The Company will not be in breach of any obligation to keep any of the Results or other information of the University, confidential or not to disclose them to any third party by making them available to any Group Company, or any person working for or on behalf of the Company or a Group Company, who needs to know the same in order to exercise the rights granted in clause 4.5, provided they are not used except as expressly permitted by

this Agreement and the recipient undertakes to keep those Results or that information confidential.

6.5 If the University receives a request under the Freedom of Information Act 2000 to disclose any information that, under this Agreement, is the Company's Confidential Information, it will notify the Company and will consult with the Company. The Company will respond to the University within 10 days after receiving the University's notice if that notice requests the Company to provide information to assist the University to determine whether or not an exemption to the Freedom of Information Act applies to the information requested under that Act.

6.6 Neither the University nor the Company will use the other's name or logo in any press release or product advertising, or for any other promotional purpose, without first obtaining the other's written consent[; except that the University may identify the sums received from the Company in the University's Annual Report and similar publications].

7. **LIMITATION OF LIABILITY**

7.1 The Materials are experimental in nature and the Company makes no representation and gives no warranty, condition or undertaking in relation to them. Without limiting the foregoing, the Company gives no warranty or condition that the Materials and their use will not infringe any third-party rights or that they have been tested for and are free from pathogens that they are viable, safe, or non-toxic.

7.2 Neither party accepts any responsibility for any use which may be made by the other party of any of the Results or the Improvements, nor for any reliance which may be placed on any Results or Improvements, nor for advice or information given in connection with any Results or Improvements.

7.3 Subject to clause 7.5, the liability of either party to the other for any breach of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement, the Project, the Results and the Improvements, will not extend to any indirect damages or losses, or any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity, whether direct or indirect, even if even if the party bringing the claim has advised the other of the possibility of those losses or if they were within the other party's contemplation.

7.4 Subject to clause 7.5, the aggregate liability of each party to the other for all and any breaches of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement, the Project, the Results and the Improvements, will not exceed [*insert amount*].

7.5 Nothing in this Agreement limits or excludes either party's liability for:

7.5.1 death or personal injury;

7.5.2 any fraud or for any sort of liability that, by law, cannot be limited or excluded; or

7.5.3 any loss or damage caused by a deliberate breach of this Agreement.

7.6 The express undertakings and warranties given by the parties in this Agreement are in lieu of all other warranties, conditions, terms, undertakings and obligations, whether express or implied by statute, common law, custom, trade usage, course of dealing or in any other way. All of these are excluded to the fullest extent permitted by law.

8. **TERMINATION**

8.1 Either party may terminate this Agreement with immediate effect by giving notice to the other party if:

8.1.1 the other party is in breach of any provision of this Agreement and (if it is capable of remedy) the breach has not been remedied within [30][60][90] days after receipt of written notice specifying the breach and requiring its remedy; or

8.1.2 the other party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other party's assets, or if the other party makes any arrangement with its creditors.

8.2 Unless terminated under clause 8.1, this Agreement, and the University's right to use the Materials, will come to an end on the expiry of the Term.

8.3 On the termination or expiry of this Agreement the University will, at its expense, [return the Materials to the Company at such address as the Company may notify to the University for that purpose][destroy the Materials and certify to the Company that this has been done].

8.4 Clauses 1, 4 (except clause 4.7 if the University terminates this Agreement under clause 8.1), 5, 6, 7, 8.3, 8.4 and 9 will survive the expiry of the Term or the termination of this Agreement for any reason and continue indefinitely.

9. **GENERAL**

9.1 **Notices:** Any notice to be given under this Agreement must be in writing, may be delivered to the other party by any of the methods set out in the left hand column below, and will be deemed to be received on the corresponding day set out in the right hand column:

Method of service	**Deemed day of receipt**
By hand or courier	the day of delivery
By pre-paid first class post	the second Business Day after posting

By recorded delivery post	the next Business Day after posting
By fax (provided the sender's fax machine confirms complete and error-free transmission of that notice to the correct fax number)	the next Business Day after sending or, if sent before 16.00 (sender's local time) on the Business Day it was sent

The parties' respective representatives for the receipt of notices are, until changed by notice given in accordance with this clause, as follows:

For the University:	**For the Company:**
Name:	Name:
Address:	Address:
Fax number:	Fax number:

9.2 **Headings:** The headings in this Agreement are for ease of reference only; they do not affect its construction or interpretation.

9.3 **Assignment:** Neither party may assign or transfer this Agreement as a whole, or any of its rights or obligations under it, without first obtaining the written consent of the other party. That consent may not be unreasonably withheld or delayed.

9.4 **Illegal/unenforceable provisions:** If the whole or any part of any provision of this Agreement is void or unenforceable in any jurisdiction, the other provisions of this Agreement, and the rest of the void or unenforceable provision, will continue in force in that jurisdiction, and the validity and enforceability of that provision in any other jurisdiction will not be affected.

9.5 **Waiver of rights:** If a party fails to enforce, or delays in enforcing, an obligation of the other party, or fails to exercise, or delays in exercising, a right under this Agreement, that failure or delay will not affect its right to enforce that obligation or constitute a waiver of that right. Any waiver of any provision of this Agreement will not, unless expressly stated to the contrary, constitute a waiver of that provision on a future occasion.

9.6 **No agency:** Nothing in this Agreement creates, implies or evidences any partnership or joint venture between the parties, or the relationship between them of principal and agent. Neither party has any authority to make any representation or commitment, or to incur any liability, on behalf of the other.

9.7 **Entire agreement:** This Agreement constitutes the entire agreement between the parties relating to its subject matter. Each party acknowledges that it has not entered

into this Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Agreement. Each party waives any claim for breach of this Agreement, or any right to rescind this Agreement in respect of any representation which is not an express provision of this Agreement. However, this clause does not exclude any liability which either party may have to the other (or any right which either party may have to rescind this Agreement) in respect of any fraudulent misrepresentation or fraudulent concealment prior to the execution of this Agreement.

9.8 **Formalities:** Each party will take any action and execute any document reasonably required by the other party to give effect to any of its rights under this Agreement, or to enable their registration in any relevant territory provided the requesting party pays the other party's reasonable expenses.

9.9 **Amendments:** No variation or amendment of this Agreement will be effective unless it is made in writing and signed by each party's representative.

9.10 **Third parties:** No one except a party to this Agreement has any right to prevent the amendment of this Agreement or its termination, and no one except a party to this Agreement may enforce any benefit conferred by this Agreement, unless this Agreement expressly provides otherwise.

9.11 **Governing law:** This Agreement is governed by, and is to be construed in accordance with, English law. The English Courts will have exclusive jurisdiction to deal with any dispute which has arisen or may arise out of, or in connection with, this Agreement, except that either party may bring proceedings for an injunction in any jurisdiction.

9.12 **Escalation:** If the parties are unable to reach agreement on any issue concerning this Agreement within 14 days after one party has notified the other of that issue, they will refer the matter to [*insert officer*] in the case of the University, and to [*insert officer*] in the case of the Company in an attempt to resolve the issue within 14 days after the referral. Either party may bring proceedings in accordance with clause 9.11 if the matter has not been resolved within that 14 day period, and either party may apply to the court for an injunction whether or not any issue has been escalated under this clause.

SIGNED for and on behalf of the University: **SIGNED** for and on behalf of the Company:

Name

Name

Position

Position

Signature

Signature

[Read and understood by the Principal

Investigator

……..

Signature

……..

Date]

SAMENVATTING

SAMENVATTING

In dit boek wordt onderzocht welke beperkingen in Italië, Engeland en de EU van toepassing zijn op de geldigheid van overeenkomsten inzake menselijk weefsel. Voor het vaststellen van die beperkingen spitst het boek zich toe op de volgende mogelijke contractrelaties voor het vervoer en gebruik van menselijk weefsel: a) overeenkomsten om niet tussen de eerste overdrager en de eerste ontvanger; b) overeenkomsten onder bezwarende titel tussen de eerste overdrager en de eerste ontvanger; c) overeenkomsten tussen de eerste en volgende ontvangers.

Er is om verschillende redenen gekozen voor Italië en Engeland als casestudy's. In de eerste plaats is Italië het enige Europese land dat vanaf het begin een bepaling inzake het beschikbaar stellen van het menselijk lichaam opnam in zijn burgerlijk wetboek (artikel 5 BW). Dit feit heeft geleid tot uitgebreide wetenschappelijke literatuur over de juridische status van het menselijk lichaam en delen daarvan. In de tweede plaats kent Engeland, anders dan veel andere Europese landen, speciale wetgeving inzake het gebruik van menselijk weefsel, te weten de *Human Tissue Act 2004* ('Wet Menselijk Lichaamsmateriaal'). Deze bijzondere omstandigheden in elk van de onderzochte landen maakten het mogelijk een interessante vergelijkende analyse te maken van de beperkingen van de geldigheid van overeenkomsten inzake menselijk weefsel. In Italië vormde een relatief oude (1942) bepaling in het burgerlijk wetboek het oorspronkelijke kader voor het vaststellen van deze beperkingen, terwijl in Engeland het gebruik van menselijk weefsel uitvoerig wordt geregeld in een relatief nieuw wetsinstrument. In de derde plaats is voor deze twee landen gekozen omdat ze tot verschillende rechtsfamilies en -tradities behoren.

Dit boek is onderverdeeld in zeven **Delen**, die op hun beurt weer zijn onderverdeeld in hoofdstukken, alinea's en paragrafen.

Deel 2 is gewijd aan een analyse van internationale en supranationale rechtsbronnen die de geldigheid van overeenkomsten inzake menselijk weefsel direct dan wel indirect beperken.
Hiertoe worden in hoofdstuk 2 rechtsbronnen voor grond- of mensenrechten op nationaal en supranationaal niveau onderzocht die mogelijk van toepassing zijn in de rechtssystemen van Engeland en Italië. In Italië beperken de relevante normen van de UVRM, de EVRM, het Oviedo-verdrag en het Handvest van de grondrechten van de Europese Unie de geldigheid van overeenkomsten inzake menselijk weefsel. In Engeland zijn mogelijk alleen de relevante bepalingen van de *Human Rights Act 1998* en het Oviedo-verdrag van invloed op de interpretatie of bepaling van de geldigheid van dergelijke overeenkomsten.
In hoofdstuk 3 wordt ook onderzocht op welke wijze de AVG direct en indirecte beperkingen kan opleggen aan de geldigheid van overeenkomsten inzake

menselijk lichaamsmateriaal. Ten eerste is een overeenkomst inzake menselijk lichaamsmateriaal die de verwerking van persoonsgegevens omvat, gehouden aan de beginselen van de AVG: rechtmatigheid, behoorlijkheid en transparantie, het doelbeginsel, dataminimalisatie, nauwkeurigheid, opslagbeperking en integriteit, en vertrouwelijkheid. Deze beginselen zijn niet van toepassing op anonieme informatie. Gepseudonimiseerde gegevens zijn niet uitgesloten van toepassing van de beginselen van de AVG. Ten tweede verbiedt de AVG, enkele uitzonderingen daargelaten, de verwerking van bijzondere categorieën persoonsgegevens, bijvoorbeeld genetische en gezondheidsgegevens. Ten derde schrijft de AVG de voorwaarden voor toestemming voor de verwerking van persoonsgegevens voor. Ten slotte schrijft de AVG voor welke informatie door de verwerkingsverantwoordelijke aan de betrokkene moet worden verstrekt. In hoofdstuk 3 wordt ook geanalyseerd hoe, en in welke mate, de nationale gegevensbeschermingsregelingen in Italië en Engeland de AVG versterken, veranderen of daarvan afwijken.

In **Deel 3** en **Deel 4** worden de nationale rechtssystemen in respectievelijk Italië en Engeland geanalyseerd. Om te komen tot een algemeen overzicht van de rechtsbronnen die beschikbaar zijn voor het analyseren van de beperkingen van de geldigheid van overeenkomsten, beginnen beide delen met een beschrijving van het meerlagige stelsel van rechtsbronnen voor de vaststelling van dergelijke beperkingen (hoofdstuk **4** in Italië en hoofdstuk **13** in Engeland).

Deel 3 gaat over Italië en omvat de hoofdstukken 4 tot en met 12. In hoofdstuk **5** wordt een overzicht gegeven van het begrip 'ongeldigheid van overeenkomsten' volgens Italiaans recht, dat mogelijk van invloed is op de geldigheid van overeenkomsten inzake menselijk weefsel. Dit begrip biedt een kader voor het analyseren van het verband tussen de geldigheid van overeenkomsten inzake menselijk weefsel en: a) dwingende normen van internationale en supranationale rechtsbronnen (bijv. de AVG); b) grondrechten in supranationale en nationale wetgeving. In hoofdstuk **6** wordt ingezoomd op de rechtsstatelijke normen en rechten die relevant zijn voor het bepalen van een normatief kader voor de regulering van het ter beschikking stellen van het menselijk lichaam en delen daarvan. In hoofdstuk 6 wordt daarnaast de horizontale werking van grondrechten geanalyseerd, voor zover relevant voor de geldigheid van overeenkomsten inzake menselijk weefsel. Hoofdstuk **7** heeft een tweeledig doel. Ten eerste wordt een uitgebreid overzicht gegeven van de wetshistorie van artikel 5 van het Italiaanse burgerlijk wetboek en de historische achtergrond en regelgevingsdoeleinden ervan. Ten tweede worden de beperkingen geanalyseerd die artikel 5 van het burgerlijk wetboek stelt aan het ter beschikking stellen van het menselijk lichaam en delen daarvan, te weten de blijvende aantasting van de lichamelijke integriteit van de betrokkene, de openbare orde en de goede zeden. Hoofdstuk **8** is gewijd aan artikel 50 van het wetboek van strafrecht, dat, voordat

de Italiaanse grondwet in werking trad, samen met artikel 5 van het burgerlijk wetboek het ter beschikking stellen van het menselijk lichaam en delen daarvan regelde en dat de rechtsgrondslag vormt voor de doctrine inzake toestemming voor ingrepen in iemands lichaam. In hoofdstuk **9** wordt ingegaan op het verbod op financieel gewin, een algemeen beginsel op basis waarvan het menselijk lichaam en delen daarvan, waaronder menselijk weefsel, geen bron van financieel gewin mogen zijn. Hoofdstuk 9 brengt in dit kader de supranationale en nationale rechtsbronnen in kaart waaruit het algemene beginsel van financieel gewin voortkomt, alsmede de mogelijke werkingssfeer daarvan. Hoofdstuk **10** verkent door Italiaanse wetenschappers aangevoerde argumenten voor of tegen de rechtmatigheid van dergelijke vervoerscontracten inzake menselijk weefsel die tussen de eerste overdrager en de eerste ontvanger worden gesloten met een winstoogmerk. Hoofdstuk **11** bevat een analyse van enkele praktijkvoorbeelden van afdwingbare overeenkomsten voor het gebruik van menselijk weefsel volgens Italiaans recht. In hoofdstuk 11 worden in het bijzonder twee specifieke model-MTA-overeenkomsten (overeenkomsten inzake materiaaloverdracht) voor het vervoer van menselijk weefsel geanalyseerd. In hoofdstuk **12** worden enkele slotopmerkingen gepresenteerd over de beperkingen van de geldigheid van overeenkomsten inzake menselijk weefsel volgens Italiaans recht.

Deel 4 over Engeland omvat de hoofdstukken 13 tot en met 19.

In hoofdstuk **14** wordt een uitgebreid overzicht gegeven van de *Human Tissue Act 2004*, de belangrijkste wetgeving inzake het gebruik en de opslag van menselijk weefsel in Engeland en Wales. Dit hoofdstuk gaat met name in op de bepalingen die (direct dan wel indirect) relevant zijn voor het vaststellen van de beperkingen van de geldigheid van overeenkomsten inzake menselijk weefsel. Hoewel de *Human Tissue Act 2004* de toestemming voor het gebruik en de opslag van menselijk weefsel van levende personen regelt, regelt de wet niet de toestemming voor medische behandeling en medisch onderzoek. Dit wordt geregeld door het gemene recht. Hoofdstuk **15** is daarom gewijd aan het geven van toestemming voor het verwijderen van weefsel van levende personen in Engeland en Wales. In hoofdstuk **16** wordt een overzicht gegeven van de doctrines van onrechtmatigheid en openbaar beleid in het gemene recht, voor zover relevant voor de geldigheid van overeenkomsten inzake menselijk weefsel. In de eerste plaats wordt verwezen naar de wetenschappelijke taxonomie van onrechtmatigheid. In de tweede plaats worden de algemene kenmerken van de doctrine van openbaar beleid besproken. In de derde plaats worden er zeven vormen van onrechtmatigheid en/of openbaar beleid genoemd die mogelijk beperkingen vormen van de geldigheid van overeenkomsten inzake menselijk weefsel: overeenkomsten die leiden tot een onrechtmatige daad, overeenkomsten bedoeld om een misdrijf te plegen, overeenkomsten bedoeld

om een onrechtmatige gedraging te verrichten of fraude te plegen, overeenkomsten die op zichzelf wettig zijn maar worden aangewend voor een onwettig doeleinde, overeenkomsten waarin een onwettige uitvoeringswijze is opgenomen, overeenkomsten die de persoonlijke vrijheid beperken, en overeenkomsten die in strijd zijn met de goede zeden. Deze zeven vormen zijn relevant voor ten minste vier aspecten van het onderwerp van dit boek. Ten eerste voor het bepalen van de beperkingen van de geldigheid van overeenkomsten inzake menselijk weefsel die voortkomen uit rechtsbronnen, zoals het geval is bij overeenkomsten die leiden tot een onrechtmatige daad en overeenkomsten bedoeld om een misdrijf te plegen ten aanzien van de normatieve bepalingen van de *Human Tissue Act* (bijv. artikel 32 van de *Human Tissue Act*). Ten tweede voor het analyseren van andere relevante rechtsbronnen die een aanvulling vormen op de rechtsregeling inzake de verwijdering, het gebruik en de opslag van menselijk weefsel, en met name voor het analyseren van de overeenkomsten bedoeld om een onrechtmatige gedraging te verrichten of fraude te plegen ten aanzien van de rechtsregeling voor toestemming op grond van het gemene recht. Ten derde voor het beoordelen van de geldigheid van overeenkomsten inzake menselijk weefsel wanneer de doelen van de overeenkomst niet expliciet of impliciet bij wet geregeld zijn (bijv. het gebruik van menselijk weefsel voor kunstwerken). Ten vierde voor de rol die het begrip 'goede zeden' mogelijk speelt bij het bepalen van de geldigheid van overeenkomsten met een zeer omstreden zedelijke inhoud (bijv. overeenkomsten ten behoeve van de verkoop van menselijk weefsel). In hoofdstuk **17** wordt ingegaan op de uitwerking van grondrechten op particuliere betrekkingen volgens Engels recht. Er wordt eerst een kort overzicht gegeven van het verband tussen privaatrecht en grondrechten in Engeland. Daarna worden de verschillende theorieën over de horizontale werking van grondrechten kort besproken, en wordt de relevantie beoordeeld van het beginsel van menselijke waardigheid, volgens Engels recht in het algemeen en volgens het contractrecht in het bijzonder. Uit de analyse in dit hoofdstuk kan worden afgeleid dat de in de *Human Rights Act* verankerde mensenrechten ten minste een indirecte horizontale werking hebben tussen particuliere partijen, en (indirecte) beperkingen zouden kunnen vormen voor de geldigheid van overeenkomsten inzake menselijk weefsel. Wat betreft, in het bijzonder, het beginsel van menselijke waardigheid, kan redelijkerwijs worden gesteld dat dit beginsel mogelijk een rol speelt bij de bepaling van de beperkingen van de geldigheid van overeenkomsten volgens Engels recht. In hoofdstuk **18** wordt een analyse gegeven van enkele praktijkvoorbeelden van afdwingbare overeenkomsten voor het gebruik van menselijk weefsel volgens Engels recht. Er zijn in het bijzonder twee soorten MTA's verzameld en bestudeerd. De eerste soort overeenkomsten wordt gesloten tussen universiteiten onderling of binnen universiteiten of soortgelijke instellingen (bijv. onderzoekscentra). Deze soort overeenkomsten is doorgaans gericht op het doen van wetenschappelijk

onderzoek zonder winstoogmerk. In de tweede soort overeenkomsten is ten minste een van de partijen een bedrijf. In het laatste geval kan de werkingssfeer van het contract variëren en kan deze onderzoek met commerciële doeleinden omvatten. Om de lezer een voorbeeld te geven van de vele soorten (typische en atypische) overeenkomsten die ten behoeve van het gebruik van menselijk weefsel gesloten kunnen worden, wordt in dit hoofdstuk ten slotte een soort overeenkomst bestudeerd die niet voldoet aan de standaardstructuur van een MTA: de *SGC Open Science Trust Agreement*. In hoofdstuk **19** worden enkele slotopmerkingen gepresenteerd over de beperkingen van de geldigheid van overeenkomsten inzake menselijk weefsel volgens Engels recht.

Deel 5 is gewijd aan een vergelijkende analyse van de beperkingen van de geldigheid van overeenkomsten inzake menselijk weefsel in Italië en Engeland, zoals aangevuld door de supranationale rechtsbronnen in de Europese Unie. De inhoud van deel 5 is als volgt: alinea 20.2 geeft een vergelijkende analyse van de soorten overeenkomsten inzake menselijk weefsel die expliciet door de wet zijn verboden dan wel toegestaan. Verschillende beperkingen van de geldigheid van overeenkomsten inzake menselijk weefsel die voortkomen uit de analyse van de verschillende rechtsbronnen, zijn in gelijke mate op meer dan een van de drie soorten overeenkomsten die in dit werk worden besproken van toepassing, te weten overeenkomsten om niet en overeenkomsten onder bezwarende titel tussen de eerste overdrager en de eerste ontvanger en overeenkomsten tussen de eerste en volgende ontvangers. Alinea 20.3 bevat daarom een vergelijking van de beperkingen van de geldigheid van overeenkomsten inzake menselijk weefsel in de rechtssystemen van Italië en Engeland die, ingevolge hun niet-belangeloze aard of de positie van de contractpartijen, niet specifiek van toepassing zijn op een bepaald soort contract. Aangezien de niet-belangeloze elementen van de overeenkomst en de positie van de contractpartijen aanleiding geven tot bepaalde beperkingen die om een onafhankelijke analyse vragen, geven de alinea's 20.4 en 20.5 een vergelijking van de beperkingen van de geldigheid van, respectievelijk, overeenkomsten onder bezwarende titel en overeenkomsten tussen de eerste en volgende ontvangers, voor zover die onderscheidende kenmerken en beperkingen hebben die vragen om een onafhankelijke benadering. De interne structuur van deze alinea's komt overeen met de voornaamste overeenkomsten en verschillen tussen de geanalyseerde rechtssystemen (bijv. gegevensbescherming, toestemming, menselijke waardigheid).

In **Deel 6** wordt het standpunt van dit boek gepresenteerd over een aantal zaken die in de delen daarvoor zijn besproken. Dit deel valt in twee hoofdstukken uiteen. In het eerste (hoofdstuk **21**) worden, vanuit een theoretisch perspectief, en zonder verwijzing naar enig nationaal recht, twee zaken geanalyseerd die verband houden met de geldigheid van overeenkomsten om niet inzake

menselijk weefsel die worden gesloten tussen de eerste overdrager en de eerste ontvanger: a) de vorm en geldigheid van toestemming en b) de problemen in verband met de anonimisering en commodificatie van weefselmonsters. In het tweede (hoofdstuk **22**) wordt ingezoomd op twee aspecten van de geldigheid van overeenkomsten onder bezwarende titel inzake menselijk weefsel die worden gesloten tussen de eerste overdrager en de eerste ontvanger: a) het verband tussen autonomie en paternalisme in deze soort overeenkomsten; b) de grenzen aan paternalisme en; c) regulering en zelfregulering ten behoeve van de bescherming van de belangen en rechten van de partijen die betrokken zijn bij het sluiten van overeenkomsten inzake menselijk weefsel.

In **Deel 7,** ten slotte, wordt een aantal conclusies en aanbevelingen gepresenteerd en worden enkele ideeën naar voren gebracht voor een verder debat over het ten behoeve van onderzoek sluiten van overeenkomsten inzake menselijk weefsel.

B

BIBLIOGRAPHY

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Literature

Alpa & Ansaldo 2013: Guido, Alpa and Anna, Ansaldo. "Le persone fisiche: artt. 1-10" in *Comm. Schlesinger*, 360-402. Milan: Giuffré, 2013, 2nd edition.

Alpa 1995: Alpa, Guido. "Libertà Contrattuale e tutela costituzionale*." Riv. critica dir. privato*, 1995.

Alpa 1999: Alpa, Guido. "L'applicabilità della Convenzione europea sui diritti dell'uomo ai rapporti tra privati." *Europa e diritto privato* 3 (1999): 873-884.

Alpa 2000: Alpa, Guido. *Trattato di Diritto Civile. Vol. I*. Milano: Giuffrè, 2000.

Alpa 2002: Alpa, Guido. *Istituzioni di diritto privato. Problemi*. Torino: UTET, 2002.

Alpa 2005: Alpa, Guido. *Manuale di Diritto Privato, Quarta Edizione*. CEDAM, 2005.

Amato 1967: Amato, Giuliano. *Individuo e autorità nella disciplina della libertà corporale*. Milano: Giuffrè, 1967.

Andorno 2009: Andorno, Roberto. "Human dignity and human rights as a common ground for a global bioethics." *Journal of Medicine and Philosophy* 34, no. 3 (2009): 223-240.

Ashcroft 2005: Ashcroft, Richard E. "Making sense of dignity." *Journal of medical ethics 31*, no. 11 (2005): 679-682.

Bamforth 2001: Bamforth, Nicholas. "The True "Horizontal Effect" of the Human Rights Act 1998'(2001)." *LQR* 117: 34.

Barbera 1975: Barbera, Augusto. "Articolo 2. Principi fondamenali." In: *Commentario della Costituzione. Principi fondamentali*, edited by, G. Branca (ed.), 50-122. Bologna/Roma: Nicola Zanichelli Editore/Foro Italiano, 1975.

Barbera 1997: Barbera, Augusto. *I principi costituzionali della libertà personale*. Milano: Giuffrè, 1997.

Barile 1984: Barile, Paolo. *Diritti dell'uomo e libertà fondamentali*. Bologna: Il Mulino, 1984.

Barile 1991: Barile, Paolo. *Istituzioni di diritto pubblico*. CEDAM, 1991.

Barile 1994: Barile, Paolo, "Eguaglianza e tutela della diversità nella Costituzione'. *Quaderni Costituzionali*, 1994.

Beale & Pittam 2001: Beale, Hugh, and Nicola Pittam. "The impact of the Human Rights Act 1998 on English tort and contract law." In *Human rights in private law,* edited by Friedmann & Barak-Erez, 131-159. Hart Publishing, 2001.

Beale 2012: Beale, Hugh, W. D. Bishop, & M.P. Furmston, *Contract. Cases & Materials. Chitty on contracts. Vol. 1*. Sweet & Maxwell, 2012.

Beatson, Burrows, Cartwright 2010: Anson, William Reynell, Jack Beatson, Andrew S. Burrows, and John Cartwright. *Anson's law of contract*. Oxford University Press, 2010.

Bellivier & Noiville 2004: Bellivier, Florence and Christine Noiville. "La circulation du vivant humain: modèle de la propriété ou modèle du contrat." In *Code civil et modèles. Des modèles du Code au Code comme modèle*, edited by Revet T. Paris: Presses de la Sorbonne 101, 2005.

Bellivier & Noiville 2004: Bellivier, Florence, and Christine Noiville. "The commercialisation of human biomaterials: what are the rights of donors of biological material?." *Journal of International Biotechnology Law 1*, no. 3 (2004): 89-97.

Bellivier & Noiville 2005: Bellivier, Florence, and Christine Noiville. "La circulation du vivant humain: modèle de la propriété ou modèle du contrat." *Revet T (sous la direction de). Code civil et modèles. Des modèles du Code au Code comme modèle. Bibliothèque de l'Institut André Tunc. Paris: Presses de la Sorbonne* 101 (2005)

Bellivier & Noiville 2006: Bellivier, Florence. "Contrats et vivant: le droit de la circulation des ressources biologiques." (2006).

Bellivier & Noiville 2009: Bellivier, Florence, and Christine Noiville. Les biobanques. Vol. 3848. Presses Universitaires de France-PUF, 2009.

Bellivier 2006: Bellivier, Florence. *Contrats et vivant: le droit de la circulation des ressources biologiques*. Paris: Librairie générale de droit et de jurisprudence, 2006.

Bernard 2008: Barnard, Catherine. "The 'Opt-Out' for the UK and Poland from the Charter of Fundamental Rights: Triumph of Rhetoric over Reality?." In *The*

Lisbon Treaty. EU Constitutionalism without a Constitutional Treaty edited by Stefan Griller, Jacques Ziller, 257. ECSA, 2008.

Bessone & Ferrando 1983: Bessone, Mario and Ferrando, Gilda. "Voce: persona fisica. In *Enciclopedia del Diritto*, 1983.

Bessone 1972: Bessone, Mario. ""Causa" e "motivo" nella disciplina del testamento." *Giur. it.,* 1972.

Beyleveld & Brownsword 2001: Beyleveld, Deryck and Brownsword Roger. *Human dignity in bioethics and biolaw*. Oxford: Oxford University Press, 2001.

Beyleveld & Brownsword 2007: Beyleveld, Deryck and Brownsword Roger. *Consent in the Law*. Bloomsbury Publishing, 2007.

Beyleveld and Brownsword 1998: Beyleveld, Dryck and Brownsword, Roger (1998). "Human dignity, human rights, and human genetics." *Mod. L. Rev*., 61, 661.

Bianca 1999: Bianca, Cesare Massimo. *Diritto civile: il contratto. Vol. 3*. Giuffrè, 2000.

Bianca, G. Patti, S. Patti 1995: Bianca, Cesare Massimo and Patti, Salvatore. *Lessico di diritto civile*. Milano: Giuffrè, 1995.

Bin & Pitruzzella 2000: Bin, Roberto and Pitruzzella, Giovanni. *Diritto Costituzionale*. Torino: Giapichelli 2000.

Binder & Lades 2015: Binder, Martin, and Leonhard K. Lades. "Autonomy-Enhancing Paternalism." *Kyklos* 68, no. 1 (2015): 3-27.

Bronzini 2012: Bronzini, Giuseppe. "Le tutele dei diritti fondamentali e la loro effettività: il ruolo della Carta di Nizza." *Riv. giur. lav,* 1, no. 63 (2012): 53.

Brownsword 2001: Brownsword, Roger. "Freedom of contract, human rights and human dignity." In *Human rights in private law,* edited by Friedmann & Barak-Erez. Hart Publishing, 2001.

Brüggemeier, Colombi Ciacchi and Giovanni Comandé 2010: Brüggemeier, Gert, Aurelia Colombi Ciacchi, and Giovanni Comandé (eds). Fundamental Rights and Private Law in the European Union: Comparative analyses of selected case patterns. Vol. 2. Cambridge University Press, 2010.

Buxton 2000: Buxton, Richard. "The Human Rights Act and Private Law". *LQR* 116 (2000): 48.

Cafaggi 2006: Cafaggi, Fabrizio. *The institutional framework of European private law*. Oxford: Oxford University Press, 2006.

Caggia & Resta 2019: Caggia, Fausto, and Resta Giorgio (eds.). *I diritti fondamentali in Europa e il diritto privato*. Roma: Roma 3 Press, 2019.

Caggia 2005: Caggia, Fausto. "Sub art. 5". In *Codice Civile Commentato*, editd by G. Alpa - V. Mariconda, 218, Milano: Ipsoa, 2005.

Camardi 2016: Camardi, Carmela. *Contratti. Parte generale, Diritto Privato*. Padova: Wolters Kluwer - CEDAM, 2016.

Cambon-Thomsen 2004: Cambon-Thomsen, Anne. "The social and ethical issues of post-genomic human biobanks." *Nature Reviews Genetics* 5, no. 11 (2004): 866.

Campanelli 2005: Campanelli, Giuseppe. "Linee giurisprudenziali della Corte costituzionale e della Corte di cassazione in tema di atti di disposizione del proprio corpo". In *Biotecnologie e valori costituzionali. Il contributo della giustizia costituzionale*, edited by A. D'Aloia, 195. Torino: Giappichelli, 2005.

Capps 2009: Capps, Patrick. *Human dignity and the foundations of international law*. Bloomsbury Publishing, 2009.

Cappuccio 2018: Cappuccio, Laura. "L'efficacia diretta orizzontale della Carta dei diritti fondamentali nella decisione Vera Egenberger." *Quaderni costituzionali* 38, no. 3 (2018): 708-710.

Carusi 1995: Carusi, Donato. *Contratto illecito e solute retention. L'art. 2035 cod. civ. tra vecchie e nuove 'immoralità'*,. Napoli: Jovene, 1995.

Carusi 1998: Carusi, Donato. "Voce <<Atti di disposizione del proprio corpo>>". In *Enc. Giur. Treccani*, III. Roma: Ed. Enc. It., 1998.

Casabona 2011: Romeo Casabona, Carlos María. *Enciclopedia de bioderecho y bioética*. Granada: Comares, 2011.

Casonato 2006: Casonato, Carlo. "Bioetica e pluralismo nellos Stato costituzionale, in *Biodiritto in dialogo* dited by C. Casonato and C. Piciocchi, 7. Padova: Cedam, 2006.

Caulfield & Brownsword 2006: Caulfield, Timothy, and Roger Brownsword. "Human dignity: a guide to policy making in the biotechnology era?." *Nature Reviews Genetics* 7, no. 1 (2006): 72.

Ceccherini 1978: Grazia Ceccherini, Maria Leonoarda Loi and Marina Santilli, 'L'art. 32 nella giurisprudenza costituzionale'. In *Tutela della salute e Diritto Privato,* edited by Francesco Donato Busnelli and Umberto Breccia. Giuffrè Editore 1978.

Celotto 2003: Celotto, Alfonso. "Carta dei diritti fondamentali e Costituzione italiana: verso il «trattato costituzionale» europeo." *Europa e Diritto Privato* 33 (2003).

Cendon & Baldassari: Cendon, Paolo and Baldassari Augusto (eds), *Codice Civile annotato con la giurisprudenza.* UTET giuridica, 2006.

Cerri 1982: Cerri, Augusto. "La Costituzione ed il Diritto Privato". In *Trattato di Diritto Privato, premesse e disposizioni*, edited by P. Rescigno Pietro Rescigno. Torino: UTET, 1982.

Chen 2008: Chen, Jim. "Biolaw: Crackling the Code." *U. Kan. L. Rev.* 56 (2007): 1029.

Cherednychenko 2007: Cherednychenko, Olha. *Fundamental Rights. Contract Law and the Protection of the Weaker Party. A comparative Analysis of the Constitutionalisation of contracts law. Emphasis on Risky Financial Transactions.* Sellier, 2007.

Cherubini 1978: Cherubini, Maria Carla. "Tutela della saulute e c.d. atti di disposizione del corpo". In *Tutela della salute e diritto private,* edited by Francesco Donato Busnelli and Umberto Breccia. Giuffré Editore, 1978.

Chieffi 2000: Chieffi, Lorenzo. "Introduzione. Una bioetica rispettosa dei valori costituzionali". In *Biotica e Diritti dell'uomo,* edited by Chieffi Lorenzo, XI. Torino: Paravia, 2000.

Cian & Trabucchi 2014: Cian, Giorgio and Trabucchi Alberto. *Commentario Breve al Codice Civile*. Padova: Breviaria iuris, 2014.

Collins 2011: Collins, Hugh. 'The constitutionalization of European Private Law as a path to social JusticeI. In *The Many Concepts of Social Justice in European Private Law*, edited by Hans-W. Micklitz. Cheltenham: Edward Elgar Publishing 2011.

Collins 2014: Collins, Hugh. "On the (in) compatibility of human rights discourse and private law." In *Constitutionalization of European Private Law*, edited by Hans-W. Micklitz, 26-58. Oxford: Oxford Univrsity Press, 2014.

Colombi Ciacchi 2008: Colombi Ciacchi, Aurelia. “Social Rights, Human Dignity and European Contract Law”. In *Constitutional values and European contract law*, edited by Grundmann, Stefan. Kluwer Law International BV, 2008.

Colombi Ciacchi 2010: Colombi Ciacchi, Aurelia. "Party autonomy as a fundamental right in the European Union." *European Review of Contract Law* 6, no. 3 (2010): 303-318.

Colombi Ciacchi 2014: Colombi Ciacchi, Aurelia. “European fundamental rights, private law, and judicial governance”. In *Constitutionalization of European Private Law*, edited by Hans-W. Micklitz. Oxford: Oxford Univrsity Press, 2014.

Colombi Ciacchi 2014(1): Colombi Ciacchi, Aurelia. "Judicial governance in private law through the application of fundamental rights." *ALJ* 1 (2014): 120-134.

Colombi Ciacchi 2017: Colombi Ciacchi, Aurelia. "Political Parties’ Programmes: Examples of Governance against Human Rights?." *European Journal of Comparative Law and Governance* 4, no. 2 (2017): 105-109.

Colombi Ciacchi 2019: Colombi Ciacchi, Aurelia. "The Direct Horizontal Effect of EU Fundamental Rights: ECJ 17 April 2018, Case C-414/16, Vera Egenberger v Evangelisches Werk für Diakonie und Entwicklung eV. and ECJ 11 September 2018, Case C-68/17, IR v JQ." *European Constitutional Law Review* (2019): 1-12.

Comandé 2014: Comandé, Giovanni. *Medical Law in Italy.* Wolters Kluwer 2014.

Conti 2014: Conti, Roberto. *I giudici e il biodiritto. Un esame <<concreto>> dei casi difficili e del ruolo del giudice di merito, della Cassazione e delle Corti europee*. Roma: Aracne editrice, 2014.

Cooke 2015: Cooke, John. *Law of tort*. Pearson Education, 2007.

Criscuoli 1985: Criscuoli, Giovanni. “L’acquisto delle parti separate del proprio corpo e gli art. 820 e 821 c.c.” *Dir. fam*. 1985.

D’Addino Serravalle 1983: D’Addino Serravalle, Paola. *Atti di disposizione del corpo e tutela della persona umana.* Edizioni Scientifiche Italiane, 1983.

D’Antonio 2004: D’Antonio, Virgilio. “I dati genetici”. In *Il codice dei dati personali. Temi e problemi*, edited by F. Cardarelli-S – V. Zeno Zencovich, 337. Milano: Giuffrè, 2004.

D'Arrigo 1999: D'Arrigo, Cosimo. *Autonomia privata e integrità fisica*. Giuffrè, 1999.

D'Arrigo 2001: D'Arrigo Cosimo. "Voce <<diritto alla salute>>". In *Enc. dir. Aggiornamento*, V, 1009. Milano: Giuffrè, 2001.

D'Avack 2004: D'Avack, Lorenzo. *Verso un antidestino: biotecnologie e scelte di vita*. Giappichelli, 2004.

Dagan 2012: Dagan, Hanoch. "Pluralism and Perfectionism in Private Law." *Columbia Law Review* 112 (2012): 1409.

Dagan 2013: Dagan, Hanoch. "Autonomy, Pluralism, and Contract Law Theory." *Law & Contemp. Probs*. 76 (2013): 19.

De Cupis 1982: De Cupis, Adriano. "I diritti della personalità". In *Trattato diritto civile e commerciale* edited by Cesco e Messineo. Milano: Giuffrè, 1982.

De Franco 2007: de Franco, Rosella 'Trattamento dei dati genetici e donatore di midollo osseo". In *La protezione dei dati personali. Commentario al D. Lgs. 30 giugno 2003, n. 196 (<<Codice della* privacy*>>) Tomo II*, edited by Cesare Massimo Bianca and Francesco Donato Busnelli. CEDAM, 2007.

De Ruggiero 1931: de Ruggiero, Roberto. *Istituzioni di Diritto Civile.* Principato, 1931.

De Sola 1994: de Sola, Carlos. "Privacidad y datos genéticos. Situaciones de conflicto." *Revista de Derecho y Genoma Humano* 1 (1994).

Deakin & Markesinis 2013: Deakin, Simon and Basil Markesinis. *Markesinis and Deakin's Tort law*. Oxford University Press, 2013.

Dell'Utri 2012: Marco dell'Utri. "Delle persone (art. 1-10)". In *Commentario al Codice Civile*, directed by Enrico Gabriele. UTET, 2012.

Den Exter 2010: den Exter, André*. Human Rights and Biomedicine*. Antwerpen: Maklu, 2010.

Denis 1997: Denis, Lara. "Kant's ethics and duties to oneself." *Pacific Philosophical Quarterly* 78, no. 4 (1997): 321-348.

Di Majo 1982: Di Majo, Adolfo. *La tutela civile dei diritti*. Milano: Giuffrè, 1982.

Di Marzio 2008: Di Marzio, Fabrizio. *La nullità del contratto*. CEDAM, 2008.

Dick 2002: Lawrence, Dick "The New Paradigm: Donor Ownership of Patent Rights Through Contract Law". *The innovation journal* 1 (2002): 1.

Dickenson 2004: Dickenson, Donna. "Consent, commodification and benefit-sharing in genetic research 1." *Developing World Bioethics* 4, no. 2 (2004): 109-124.

Dogliotti 1982: Massimo Dogliotti. "Le persone fisiche." In *Trattato di Diritto Privato II*, directed by P. Rescigno. Torino, 1982.

Dogliotti 1990: Massimo Dogliotti. "Atti di disposizione del propio corpo e teoria contrattuale." *Rass. dir. civ*., (1990): 241.

Douglas-Scott 2011: Sionaidh Douglas-Scott. "The European Union and the Human Rights after the Treaty of Lisbon". *Human Rights Review* 11:4 (2011) 645-682.

Dove, Thompson, Knoppers 2016: Dove, Edward S., Beth Thompson, and Bartha M. Knoppers. "A step forward for data protection and biomedical research." *The Lancet* 387, no. 10026 (2016): 1374-1375.

Du Bois 2017: du Bois, François. "The Impact of Human Rights on English Contract Law." In *The Constitutional Dimension of Contract Law*, edited by Siliquini-Cinelli and Hutchison, 1-37. Springer Cham, 2017.

Duxbury 1996: Duxbury, Neil. "Do markets degrade?." *The Modern Law Review* 59, no. 3 (1996): 331-348.

Dworking 1988: Dworkin, Gerald. *The theory and practice of autonomy*. Cambridge University Press, 1988.

Elliot & Quinn 2013: Elliott, Catherine and Frances Quinn. *Contract law*. Pearson Education, 2013.

Farneti 2014: Farneti, Marcello. "Artt. 1-10". In *Commentario Breve al Codice Civile,* edited by Giorgio Cian. CEDAM 2014.

Fateh-Moghadam & Gutmann 2017: Fateh-Moghadam, Bijan, and Thomas Gutmann. "Governing [through] autonomy. The moral and legal limits of "soft paternalism"." *Ethical Theory and Moral Practice* 17, no. 3 (2014): 383-397.

Favilli & Fusaro 2007: Favilli Chiara & Fusaro, Carlo. "The protection of Constitutional Rights in the Private Sphere". In *Human rights and the Private*

Sphere, A comparative Study, edited by Dawn Oliver and Jörg Fedtke, 2007. London and Ney York: Routledge-Cavendish.

Feldman 1999: Feldman, David. "Human Dignity as a Legal Value: Part I." *Public Law* 4 (1999): 682-702.

Feldman 2000: Feldman, David. "Human Dignity as a Legal Value: Part II." *Public Law* 1 (2000): 61-76.

Ferrando 2002: Ferrando, Gilda. Il principio di gratuità, biotecnologie e 'atti di disposizione del corpo', in *Eur. dir. priv*., (2002): 761.

Ferrara 1914: Ferrara, Francesco. *Teoria del negozio illecito nel diritto civile italiano*. Società editrice libraria, 1914.

Ferrara 2010: Ferrara, Rosario. "Il diritto a la salute: I principi costituzionali". In *Trattato di Biodiritto, Salute e Sanitá*, directed by Stefano Rodotà e Paolo Zatti. Edited by, Rosario Ferrara. Giuffré Editore, 2010.

Ferri 1966: Ferri, Giovanni. *Causa e tipo nella teoria del negozio giuridico*. Milano 1966.

Ferri 1994: Ferri, Giovanni. *Saggi di diritto civile*. Maggioli, 1994.

Filippetta 2006: Filippetta, Giuseppe. "La libertà personale e la libertà di domicilio, di circolazione e individuale". In *I diritti costituzionali II*, edited by R. Nania and P. Ridola, 559. Torino: Giapichelli, 2006.

Floridi 2016: Floridi, Luciano. "Tolerant paternalism: Pro-ethical design as a resolution of the dilemma of toleration." *Science and engineering ethics* 22, no. 6 (2016): 1669-1688.

Gabriele & Celotto 2001: Francesco, Gabriele and Celotto Alfonso. *Fonti comunitarie e ordinamento nazionale: Temi e problemi sull'impatto del diritto comunitario nel sistema italiano delle fonti*. Cacucci, 2001.

Gajdosova & Zehetner 2010: Gajdosova Jana and Zehetner, Judith. "England" in *Fundamental rights and Private Law in the European Union Volume I: A comparative Overview,* edited by Gert Brüggemeier, Aurelia Colombi Ciacchi and Giovanni Comandé. Cambridge University Press, 2010.

Galasso 2001: Galasso, Alfredo. Biotecnologie ed atti di disposizione del corpo. *Familia*, (2001): 911.

Galati 2009: Galati, Alessandro. "La causa del contratto tra "funzione economico– sociale" e "sintesi degli interessi individuali delle parti"" In *Enciclopedia giuridica Treccani*, available at: http://www.treccani.it/magazine/diritto/approfondimenti/diritto_civile/1_Galati.html

Gazzoni 2013: Gazzoni, Francesco. *Manuale di diritto Privato.* Edizioni Scientifiche Italiane, 2013.

Gearty 2016: Gearty, Conor A. "The Human Rights Act should not be repealed." *LSE Law-Policy Briefing Paper* 16 (2016).

Gennusa 2019: Gennusa, Maria Elena. "Un nuovo pezzo del puzzle: l'effetto diretto della Carta alla prova del caso Cresco." *Quaderni costituzionali* 39, no. 2 (2019): 459-462.

Giliker 2014: Giliker, Paula. *The Europeanisation of English Tort Law*. Bloomsbury Publishing, 2014.

Gilker 2015: Giliker, Paula. "The influence of EU and European Human rights law on English private law." *International & Comparative Law Quarterly* 64, no. 2 (2015): 237-265.

Giuffrida 2000: A. Guffrida. "Il Diritto all'integrità fisica." In *Le persone (III) Diritti della personalità*, 69. Torino: UTET, 2002.

Glitter 2004: Gitter, Donna M. "Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material." *Wash. & Lee L. Rev.* 61 (2004): 257.

Gunson 2009: Gunson, Darryl. "Solidarity and the universal declaration on bioethics and human rights." *Journal of Medicine and Philosophy* 34, no. 3 (2009): 241-260.

Gutmann 2013: Gutmann, Thomas. "Some preliminary remarks on a liberal theory of contract." *Law & Contemp. Probs.* 76 (2013): 39.

Gutmann 2013: Gutmann, Thomas. *Theories of Contract and the Concept of Autonomy*. Münster: Zvi Meitar Center for Advanced Legal Studies, 2013.

Hannum 2014: Hannum, Hurst. "The status of the Universal Declaration of Human Rights in national and international law." *Ga. J. Int'l & Comp. L.* 25 (1995): 287.

Hardcastle 2007: Hardcastle, Rohan. *Law and the human body: property rights, ownership and control*. Bloomsbury Publishing, 2007.

Hartkamp 2012: Hardkamp, Arthur. *European Law and national Private Law. Effect of EU Law and European Human Rights Law on Legal relationships between individuals 2nd edition*. Cambridge, Antwerp, Portland: Intersentia, 2012.

Helgesson et al. 2007: Helgesson, Gert, Joakim Dillner, Joyce Carlson, Claus R. Bartram, and Mats G. Hansson. "Ethical framework for previously collected biobank samples." *Nature Biotechnology* 25, no. 9 (2007): 973.

Herring 2014: Herring, Jonathan. *Medical law and ethics*. USA: Oxford University Press, 2014.

Hill 2002: Hill, Anne Nichols. "One Man's Trash Is Another Man's Tresure, Bioprospecting: Protecting the Rights and Interests of Human Donors of Genetic Material." *J. Health Care L. & Pol* 5 (2002): 259.

Hockton 2002: Hockton, Andrew. *The law of consent to medical treatment*. Sweet & Maxwell Ltd, 2002.

Hofmann 2009: Hofmann, Bjørn. "Broadening consent—and diluting ethics?." *Journal of Medical Ethics* 35, no. 2 (2009): 125-129.

Holland 2001: Holland, Suzanne. "Contested commodities at both ends of life: buying and selling gametes, embryos, and body tissues." *Kennedy Institute of Ethics Journal* 11, no. 3 (2001): 263-284.

Hoppe & Miola 2014: Hoppe, Nils and Miola, José. *Medical law and medical ethics*. Cambridge University Press, 2014.

Hoppe 2011: Hoppe, Nils. "A Sense of Entitlement: Individual vs. Public Interest in Human Tissue." In *Biobanks and Tissue Research*, edited by Lenk, Christian, Sandor, Judit and Gordijn, Bert 53-64. Dordrecht: Springer, 2011.

Hoppe 2016: Lenk, Christian, and Nils Hoppe. "Using Tissue and Material from the Human Body for Biomedical Research: Proposals for a Normative Model." In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue,* edited by Peter Sýkora and Urban Wiesing, 133-141. Routledge, 2009.

Horsey & Rackley 2015: Horsey, Kirsty and Rackley Erika. *Tort Law*. Oxford University Press, 2015.

Hottois 2000: Hottois, Gilbert. "Dignity of the human body: a Philosophycal and Critical approach'. In *Bioethics and Biolaw, vol. ii: Four Ethical Principles*, edited by Peter Kemp, Jakob Rendtorff, and Niels Mattson Johansen. Rhodos International Science and Art publishers and Centre for Ethics and Law, 2000.

Hunt 1998: Hunt, Murray. "The effect on the law of obligations." In *The impact of the human rights bill on English Law*, edited by B.S. Markesini. Oxford: Clarendon Press, 1998.

Issalys 2005: Issalys, Pierre. "Choosing among forms of public action: A question of legitimacy." *Designing Government* (2005): 154-181.

Jacobson 2009: Jacobson, Nora. "A taxonomy of dignity: a grounded theory study." *BMC International health and human rights* 9, no. 1 (2009): 3.

Jiménez 2003: Jiménez, Pilar Nicolás. "Los derechos del paciente sobre su muestra biológica: distintas opiniones jurisprudenciales." *Revista de Derecho y Genoma Humano. Genética, Biotecnología y Medicina Avanzada = Law and the Human Genome Review. Genetics, Biotechnology and Advanced Medicine* 19 (2003): 207-228.

Jorion 1999: Jorion, Benoît. "La dignité de la personne humaine ou la difficile insertion d'une règle morale dans le droit positif." *Revue du Droit public et de la science politique en France et al etranger* (1999): 197-197.

Kishore 2005: Kishore, Raj R. "Human organs, scarcities, and sale: morality revisited." *Journal of Medical Ethics* 31, no. 6 (2005): 362-365.

Koepsell 2009: Koepsell, David. *Who Owns You?: The Corporate Gold Rush to Patent Your Genes*. John Wiley & Sons, 2009.

Korobkin, 2017: Korobkin, Russell. "Buying and selling human tissues for stem cell research." *Ariz. L. Rev*. 49 (2007): 45.

Krahé 2015: Krahé, Justin Friedrich. "The Impact of Public Law Norms on Private Law Relationships: Horizontal Effect in German, English, ECHR and EU Law." *European Journal of Comparative Law and Governance* 2, no. 2 (2015): 124-155.

Kronman 1983: Kronman, Anthony. "Paternalism and the Law of Contracts." *The Yale Law Journal* 92, no. 5 (1983): 763-798.

Lattanzi 2011: Lattanzi, Roberto. "Ricerca genetica e protezione dei dati personali." In *Trattato di biodiritto. Il governo del corpo Tomo I*, directed by Zatti, P. and S. Rodotà, 342. Giuffré, 2011.

Lawson 2010: Lawson, Rick. "Setting the scene: human rights and health ethics. Dwelling on the threshold: on the interaction between the European Convention on human rights and the Biomedicine convention." In *Human Rights and Biomedicine,* edited by André den Exter. Maklu, 2010.

Lenti 1993: Lenti, Leonardo. *Procreazione artificiale. Genoma della persona e attribuzione della personalità*. Padova: CEDAM, 1993.

Leonard 2008: Leonard, Thomas C. "Richard H. Thaler, Cass R. Sunstein, Nudge: Improving decisions about health, wealth, and happiness." *Constitutional Political Economy* 4, 19 (2008): 356-360.

Leonardi 1997: Leonardi, D.A. "Italy". In *European Civil Liberties and the European Convention of Human Rights*, edited by C. A. Gearty. The Hague Boston, London: Martinus Nijhoff Publushers, 1997.

Levi-Faur 2010: Levi-Faur, David. "Regulation and regulatory governance." *Handbook on the Politics of Regulation* 1, no. 1 (2011): 1-25.

Libertini 2019: Libertini, Mario. "Qualche riflessione sull'efficacia orizzontale in diritto privato delle norme sui diritti fondamentali dei Trattati europei." In *I diritti fondamentali in Europa e il diritto privato*, edited by Caggia, Fausto and Giorgio Resta. Roma: Roma 3 Press, 2019.

Lucinani 1980: Luciani, Massimo. "Il diritto costituzionale alla salute" *Dir. soc*. (1980): 769.

Lunney & Oliphant 2013: Lunney, Mark and Ken Oliphant. *Tort law: text and materials*. Oxford: Oxford University Press, 2013.

Lytvynyuk 2010: Lytvynyuk, Anna. *Fundamental rights operation in private law: a comparative study of legal solutions*. Kovač, 2010.

Macilotti 2009: Macilotti Matteo. "Consenso informato e biobanche di ricerca" *Nuova giur. Civ. Comm*. II, (2009): 153.

Maclean 2009: Maclean, Alasdair. *Autonomy, informed consent and medical law: A relational challenge*. Vol. 8. Cambridge University Press, 2009.

Mahoney 2000: Mahoney, Julia D. "The market for human tissue." *Virginia Law Review* (2000): 163-223.

Maiello 1997: Maiello, Ugo. "Le fonti del diritto privato". In *Istituzioni di diritto privato* 4th ed., edited by M. Bessone. Torino: Giapichelli, 1997.

Mak 2008: Mak, Chantal. *Fundamental rights in European contract law: a comparison of the impact of fundamental rights on contractual relationships in Germany, the Netherlands, Italy and England*. Vol. 12. Kluwer Law International BV, 2008.

Mak, Sanchez Galera, Wünsch, Ramos, Kraus 2010: Mak, Chantal, Sanchez Galera Maria Dolores, Wünsch, Sabine, Ramos Jorge and Kraus, Caroline. "Italy: [national report]." In *Fundamental rights and private law in the European Union. Vol. 1: A comparative overview,* edited by G. Brüggemeier, A. Colombi Ciacchi, and G. Comandé, 325-404. Cambridge University Press, 2010.

Mansoor, 2014: Mansoor, Zeeshan. *Public Policy and good morals. A comparative study in English and Dutch contract law*. PhD Thesis. 2014.

Mantovani 1980: Mantovani, Ferrando. "La responsabilità del medico" *Riv. It. Med. Legale*, (1980): 244.

Mantovani 1983: Mantovani, Ferrando. "Trapianti e sperimentazione umana" *Riv. It. Med. Legale* (1983).

Marella 2006: Marella, Maria Rosaria. "The old and the new limits to freedom of contract in Europe." *European Review of Contract Law* 2, no. 2 (2006): 257-274.

Marella 2008: Marella, Maria Rosaria. 'Human Dignity in a Different light: European Contract Law, Social Dignity and the Retreat of the Welfare State'. In *Constitutional values and European contract law,* edited by Grundmann, Stefan. Kluwer Law International BV, 2008.

Martin Uranga et al. 2005: Uranga, Amelia Martín, Martín-Arribas, Concepción, di Donato, Jeanne-Héléne and de la Paz Manuel, Posada. *Las cuestiones ético-jurídicas más relevantes en relación con los Biobancos. Una vision a la legislación de los países membros del proyecto EuroBioBank.* Madrid: Instituto de Salud Carlos III, 2005.

Marway 2014: Marway, Herjeet, Sarah-Louise Johnson, and Heather Widdows. "Commodification of human tissue." In *Handbook of global bioethics,* edited by H. ten Have and B. Gordijn, 581-598. Dordrecht: Springer, 2014.

Mattioni 2011: Mattioni, Angelo. "Profili costituzionali della dignità." In *La dignità,* edited by Mario Napoli. Vita e pensiero, 2011.

Mazzoni 2008: Mazzoni, Cosimo Marco. "Il corpo nascosto dei giuristi" *Riv. crit. dir. priv*., (2008): 339.

McBride & Bagshaw 2013: J. Mcbride, Nicholas and Bagshaw, Roderick. *Tort Law 4th Edition*. Pearson Education Ltd, 2013.

McCrudden 2008: McCrudden, Christopher. "Human Dignity and Judicial Interpretation of Human Rights" *European Journal of International Law* 4, n. 19 (2008): 655–724.

McHale 2010: McHale, Jean. 'The legal regulation of the use of human material". In *Principles of Medical Law,* edited by Andrew Grubb Judith Laing and Jean McHale. Oxford University Press, 2010.

Messineo 1944: Messineo, Francesco. *Dottrina generale del contratto*. Giuffrè, 1944.

Messinetti 2001: Messinetti, Davide. "Principio di gratuità ed atti di disposizione del proprio corpo." In *Confini attuali dell'autonomia privata*, edited by A. Belvedere and C. Granelli. Padova: CEDAM, 2001.

Michaels 2019: Michaels, Ralf. "The functional method of comparative law." In *The Oxford Handbook of Comparative Law,* edited by Reimann, Mathias, and Reinhard Zimmermann, 345. Oxford University Press, 2019.

Miola 2010: Miola, José. "Law, Ethics and Human Tissue Research–Integration or Competition?." In *Human Tissue Research–A Discussion of the Ethical and Legal Challenges from a European Perspective,* edited by Lenk Christian, Hoppe Nils, Katharina Beier, and Claudia Wiesemann, 79-86. Oxford University Press, 2011.

Modugno 1995: Modugno, Franco. *I nuovi diritti nella Giurispudenza Costituzionale*. Torino: Giapichelli, 1995.

Monaco 2010: Monaco, Giuseppe. "La tutela della dignità umana: sviluppi giurisprudenziali e difficoltà applicative." *Politica del diritto* 42, no. 1 (2011): 45-78.

Morelli 1997: Morelli, Mario Rosario. "L'applicazione diretta della costituzione nei rapporti interindividuali" *Giust. Civ*. II (1996): 537-548.

Morelli 1999: Morelli, Mario Rosario. “Materiali per una riflessione sulla applicazione diretta delle norme costituzionali da parte dei giudici.” *Giust. Civ*. II, (1999): 3-15.

Mori 1983: Mori, Paola. "Convenzione europea dei diritti dell’uomo, Patto delle Nazioni Unite e Costituzione italiana." *Rivista di Diritto Intenazionale* (1983): 306.

Morozzo della Rocca 2004: Morozzo della Rocca. Paolo. *Autonomia privata e prestazione senza corrispettivo*. Torino: UTET, 2004.

Möslein & Riesenhuber 2009: Möslein, Florian, and Karl Riesenhuber. "Contract Governance–A draft research agenda." *European Review of Contract Law* 5, no. 3 (2009): 248-289.

Navarretta 2004: Navarretta, Emanuela. “I Danni non patimoniali nella resposabilità extracontrattuale”. In *I danni non patrimoniali. Lineamenti sistematici e guida alla liquidazione.* Edited by Emanuela Navaretta: Milano: Giuffrè, 2004.

Nelking & Andrews 1998: Nelkin, Dorothy and Lori Andrews. "Homo economicus: commercialization of body tissue in the age of biotechnology." *Hastings Center Report* 28, no. 5 (1998): 30-39.

Noiville 2016: Noiville, Christine. "Preventing Conflicts of Interests in the Field of Human Biological Materials: the ‘Contractual Model’ as an Avantgarde." In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue,* edited by Peter Sýkora and Urban Wiesing, 143-148. Routledge, 2009.

Novelli & Pietrangeli 2011: Novelli, Giuseppe and Ilenia Pietrangeli. "I campioni biologici." In *Trattato di biodiritto. Il governo del corpo Tomo I*, directed by Zatti, P. and S. Rodotà, 1027-66. Giuffrè, 2011.

O’Brien 2009: O'Brien, Stephen J. "Stewardship of human biospecimens, DNA, genotype, and clinical data in the GWAS era." *Annual Review of Genomics and Human Genetics* 10 (2009): 193-209.

Occhiocupo 1988: Occhiocupo, Nicola. *Liberazione e promozione umana nella Costituzione: unità di valori nella pluralità di posizioni*. Milano: Giuffrè, 1988.

Ogus & Van Boom 2011: Anthony Ogus and Willem Van Boom. “Introducing, Defining and Balancing “Autonomy vs Paternalism”.” In *Juxtaposing Autonomy and Paternalism in Private Law,* edited by A. Ogus and W. H. van Boom. Oxford: Hart Publishing, 2011.

Ogus 2010: Ogus, Anthony. "The paradoxes of legal paternalism and how to resolve them." *Legal Studies* 30, no. 1 (2010): 61-73.

Oliver 2007: Oliver, Dawn. "The Human Rights Act in the Private Sphere". *In Human rights and the Private Sphere, A comparative Study*, edited by Dawn Oliver and Jörg Fedtke. London and Ney York: Routledge-Cavendish, 2007.

Örücü 2012: Örücü, Esin. "Methodology of comparative law." In: *Elgar Encyclopedia of Comparative Law*, J.M. Smits (red.). Cheltenham: Edward Elgar Publishing, 2012.

Pace 1989: Pace, Alessandro. "La garanzia dei diritti fondamentali nell'ordinamento cosituzionale italiano: il ruolo del legislatore e dei giudici "commune"." *Riv. Trim. Dir. E Proc. Civ*. (1989): 685-704.

Pace 1992: Pace, Alessandro. *Problematica delle libertà costituzionali. Parte speciale*. Padova: CEDAM, 1992.

Pace 2001: Pace, Alessandro. "La limiata incidenza della CDU sulle libertà politiche in Italia." *Diritto Pubblico* 7, no. 1 (2001): 1-32.

Paladin 1965: Paladin, Livio. "Ordine pubblico." In *Novissimo Digesto Italiano XII*, 130. Torino: UTET, 1965.

Paladin 1998: Paladin, Livio. *Diritto Costituzionale*. Padova: CEDAM, 1998.

Palmeri 2010: Palmeri, Giuseppe. "Il cambiamento di sesso.". In *Trattato di biodiritto. Il governo del corpo Tomo I*, directed by Zatti, P. and S. Rodotà. Giuffrè, 2011.

Panizza & Stradella 2013: Panizza, Saulle and Elettra Stradella. *Diritto pubblico*. *Vol. 3*. Maggioli Editore, 2013.

Parisi 2004: Parisi, Annamaria Giulia. "sub art. 90". In *La nuova disciplina della privacy: commentario al D. lgs. 30 giugno 2003, n. 196,* directd by S. Sica-P.Stanzione, 385. Bologna: Zanichelli, 2004.

Perlingieri 2010: Perlingieri, Carolina. "Articoli 1-10". In *Codice civile annotato con la dottrina e la giurisprudenza* Vol. 9, directed by Perlingieri, Giovanni. Edizioni Scientifiche italiane, 2010.

Pezzini 1983: Pezzini, Barbara. "Il diritto alla salute: profili costituzionali." *Diritto e Società* 11, (1983): 21.

Phillipson 1999: Phillipson, Gavin. "The Human Rights Act, horizontal effect and the common law: a bang or a whimper." *Mod. L. Rev*. 62 (1999): 824.

Pollicino 2018: Pollicino, Oreste. "L'efficacia orizzontale dei diritti fondamentali previsti dalla Carta La giurisprudenza della Corte di giustizia in materia di digital privacy come osservatorio privilegiato." In *La Carta dei diritti fondamentali dell'Unione Europea: efficacia ed effettività,* edited by Piccone Valeria and Pollicino, Oreste, 264-300. Editoriale scienifica, 2018

Pormeister 2017: Pormeister, Kärt. "Genetic data and the research exemption: is the GDPR going too far?." *International Data Privacy Law* 7, n. 2 (2017): 137-146.

Pormeister 2018: Pormeister, Kärt. "Genetic research and applicable law: the intra-EU conflict of laws as a regulatory challenge to cross-border genetic research." *Journal of Law and the Biosciences* 5, no. 3 (2018): 706-723.

Post 2000: Post, Robert. *Dignity, autonomy, and democracy*. Institute of Governmental Studies, University of California, Berkeley 2000.

Pothier 1764: Pothier, *Traité des obligations, selon les regles tant du for de la conscience, que du for extérieur*, Volume 1, 1794.

Price 2003: Price, David. "From Cosmos and Damian to Van Velzen: the human tissue saga continues." *Medical Law Review* 11, no. 1 (2003): 1-47.

Price 2005: Price, David. "The human tissue act 2004." *Mod. L. Rev*. 68 (2005): 798.

Price 2014: Price, David. *Human tissue in transplantation and research: a model legal and ethical donation framework*. Vol. 10. Cambridge University Press, 2009.

Quigley 2014: Quigley, Muireann. "Propertisation and commercialisation: on controlling the uses of human biomaterials." *Mod. L. Rev*. 77, no. 5 (2014): 677-702.

Radin 1987: Radin, Margaret Jane. "Market-inalienability." *Harvard Law Review* (1987): 1849-1937.

Radin 1996: Radin, Margaret Jane. *Contested commodities*. Harvard University Press, 1996.

Rao 2007: Rao, Radhika. "Genes and spleens: property, contract, or privacy rights in the human body?." *Journal Law Med. Ethics*. 3, n. 35 (2007): 371-382.

Raz 1988: Raz, Joseph. *The Morality of Freedom*. Oxford: Calendon Press Oxford, 1988.

Rescigno 1982: Rescigno, Pietro. *Trattato di Diritto Privato, premesse e disposizioni*. Torino: UTET, 1982.

Resnik 2002: Resnik, David B. "The commercialization of human stem cells: ethical and policy issues." *Health Care Analysis* 10, no. 2 (2002): 127-154.

Resta 2006: Resta, Giorgio. "La persona fisica e i diritti della personalità". In *Trattato di diritto civile*, directed by R. Sacco, 361-664. Torino: UTET, 2006.

Resta 2006: Resta, Giorgio. "Contratto e persona". In *Trattato del Contratto IV Interferenze,* edited by Vincenzo Roppo. Giuffrè, 2006.

Resta 2008: Resta, Giorgio. "Do we own our bodies? Il problema dell'utilizzazione del materiale biologico umano a scopi di ricerca e brevettazione." *Pòlemos* (2008): 115.

Resta 2011: Resta, Giorgio. "La disposizione del corpo. Regole di appartenenza e di circolazione." In *Trattato di biodiritto. Il governo del corpo Tomo I*, directed by Zatti, P. and S. Rodotà. 805-848. Giuffrè 2011.

Resta 2011(1): Resta, Giorgio. "The New Frontiers of Personality Rights and the Problem of Commodification: European and Comparative Perspectives." *Tul. Eur. & Civ. LF* 26 (2011): 33.

Rodotà 2006: Rodotà, Stefano. *La vita e le regole: tra diritto e non diritto*. Feltrinelli Editore, 2006.

Rodriguez 2005: Rodriguez, Victor. "Material transfer agreements: open science vs. proprietary claims." *Nature Biotechnology*, Volume 23, Number 4, April 2005.

Rolli 2008: Rolli, Rita. *La causa in astratto e la causa in concreto*. CEDAM, 2008.

Romano 1995: Romano, Mario. *Commentario sistematico al codice penale, I*. Milano: Giuffrè, 1995.

Romboli 1991: Romboli, Roberto. "I limiti alla libertà di disporre del proprio corpo nel suo aspetto "attivo" ed in quello "passivo". " In *Foro It. I*. (1991): 15.

Romboli 1998: Romboli, Roberto. "sub art. 5". *In Commentario al Codice Civile Scialoja e Branca*, *Delle persone fisiche, artt. 1-10* edited by F. Galgano, 225. Bologna-Roma: Zanichelli, 1988.

Roppo 1977: Roppo, Vincenzo. *Il contratto.* Il mulino, 1977.

Ruggeri & Spadano 1991: Ruggeri, Antonio and Spadaro, Antonino. *Dignità dell'uomo e giurisprudenza costituzionale (prime notazioni)*. Il Mulino, 1991.

Salazar 1983: Salazar, Lorenzo. "Consenso dell'avente diritto e disponibilità dell'integrità fisica". *Cass. Pen. Mass.*, (1983): 53-55.

Santamaria 2017: Santamaría, Enrique. "Contracts on Human Biological Samples: The European Prohibition of Financial Gain from the Human Body and its Parts." *European Review of Contract Law* 13, no. 2 (2017): 195-214.

Santoro-Pasarelli 1997: Santoro-Passarelli, Francesco. *Dottrine Generali del Diritto Civile* 9ª ed. Napoli: Eugenio Jovene, 1997.

Scalisi 1990: Scalisi, Antonio. *Il valore della persona nel sistema e I nuovi diritti della personalità.* Giuffrè Editore, 1990.

Schlag, Thaler, & Sunstein 2010: Schlag, Pierre, R. H. Thaler, and C. R. Sunstein. "Nudge, Choice Architecture, and Libertarian Paternalism'." *Michigan Law Review* 108, (2010): 913.

Schroeder 2008: Schroeder, Doris. "Dignity: Two riddles and four concepts." *Cambridge Quarterly of Healthcare Ethics* 17, no. 2 (2008): 230-238.

Schroeder 2010: Schroeder, Doris. "Dignity: one, two, three, four, five, still counting." *Cambridge Quarterly of Healthcare Ethics* 19, no. 1 (2010): 118-125.

Seatzu & Fanni 2015: Seatzu, Francesco and Simona Fanni. "The Experience of the European Court of Human Rights with the European Convention on Human Rights and Biomedicine." *Utrecht J. Int'l & Eur. L.* 31 (2015): 5.

Seminara 2011: Seminara, Sergio. "La dimensione del corpo nel diritto penale" In *Trattato di biodiritto. Il governo del corpo Tomo I*, directed by Zatti, P. and S. Rodotà, 189. Giuffré, 2011.

Sharp 2000: Sharp, Lesley A. "The commodification of the body and its parts." *Annual Review of Anthropology* 29, no. 1 (2000): 287-328.

Silvestri 1993: Silvestri, Gaetano. "La tutela dei diritti fondamentali nel processo civile." *Politica del diritto* XXIV, n. 3 (1993): 479-491.

Singer 1959: Singer, Marcus G. "On duties to oneself." *Ethics* 69, no. 3 (1959): 202-205.

Sjöstrand et al. 2013: Sjöstrand, Manne, Stefan Eriksson, Niklas Juth, and Gert Helgesson. "Paternalism in the name of autonomy." In *Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine* 38, no. 6 (2013): 710-724.

Smaglik 2000: Smaglik, Paul. "Tissue donors use their influence in deal over gene patent terms." *Nature* 407, (2000): 821.

Stefanini 2009: Stefanini, Elisa. "La circolazione dei dati genetici tra vecchi diritti e nuove sfide". In *I dati genetici nel biodiritto*, edited by Carlo Casonato, Cinzia Piciocchi, Paolo Veronesi. CEDAM, 2011.

Streitz and Bennet 2003: Streitz, Wendy and Alan Bennett. "Material transfer agreements: a university perspective." *Plant Physiology* 133, no. 1 (2003): 10-13.

Sucameli 2007: Sucameli, Francesco. *L'Europa e il dilemma della costituzione. Norme, strategie e crisi del processo di integrazione*. Giuffrè Editore, 2007.

Sustein 2015: Sunstein, Cass R. *Why nudge?: The politics of libertarian paternalism*. Yale University Press, 2015.

Sýkora 2016: Sýkora, Peter. "Altruism in medical donations reconsidered: the reciprocity approach." In *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue,* edited by Peter Sýkora and Urban Wiesing, 13-49. Routledge, 2009.

Tallachini 2005: Tallacchini, Mariachiara. "Rhetoric of anonymity and property rights in human biological materials (HBMs)." *Law and the Human Genome Review* 22 (2005): 153-175.

Tamburrino, 1965: Tamburrino, Giuseppe. *Scritti giuridici in memoria di Marcello Barberio Corsetti*. Milano: Giuffrè, 1965

Taylor 2002: Taylor, Richard. "Human property: threat or saviour?." (2002). *Murdoch University Electronic Journal of Law*, Volume 9, Number 2.

Taylor 2012: Taylor, Mark. *Genetic data and the law: a critical perspective on privacy protection* Vol. 16. Cambridge University Press, 2012.

Terlizzi 2013: Terlizzi, Giulia. *Dal buon costume alla dignità della persona. Percorsi di una clausola generale*. Edizioni Scientifiche italiane, 2013.

Thaler & C. R. Sustein 2003: Sunstein, Cass R., and Richard H. Thaler. "Libertarian paternalism is not an oxymoron." *The University of Chicago Law Review* (2003): 1159-1202.

Thaler & Sunstein 2008: Thaler, Richard H., and Cass R. Sunstein. *Nudge: Improving decisions about health, wealth, and happiness*. Penguin, 2008.

Theròn 1998: Théron, Jean-Pierre. "Dignité et libertés: Propos sur une jurisprudence contestable." In *Pouvoir et liberté: études offertes à Jacques Mourgeon Bruylant,* 295-306. Brussels: Èditions Bruylant. 1998.

Titmmus 1970: Titmuss, Richard*. The gift relationship: From human blood to social policy*. The New Press, 1970.

Torrente & Schlesinger 2015: Torrente, Andrea and Schlesinger, Piero. *Manuale di Diritto Privato.* Giuffrè Editore, 2015.

Trabucchi 1959: Trabucchi, Alberto. "Buon Costume (voce)". In *Enciclopedia del Diritto*. Giuffré 1959.

Treitel, 2011: Peel, Edwin. *Treitel The Law Of Contract*, 13" Edition. London: Sweet & Maxwell 2011.

Trimarchi 1975: Trimarchi, Pietro. *Istituzioni di diritto privato*. Giuffrè Editore, 2011.

Valle 2012: Valle, Laura. "'Artt. 1-10'" in *Commentario Compatto al Codice Civile,* edited by Francesco Galgano. Casa Editrice La Tribuna, 2012.

Venuti 2001: Venuti, Maria Carmela. "Atti di disposizione del corpo e principio di gratuità". *Dir. Dam*. (2001): 827.

Venuti 2002: Venuti, Maria Carmela. *Gli atti di disposizione del corpo*. Giuffrè, 2002.

Veronesi 2011: Veronesi, Paolo. "Uno statuto costituzionale del corpo". In *Trattato di biodiritto. Il governo del corpo Tomo I*, directed by Zatti, P. and S. Rodotà, 137-172 . Giuffré, 2011.

Waddams 2011: Waddams, Stephene. "Autonomy and Paternalism from a Common Law Perspective: Settling aside disadvantageous transactions". In *Juxtaposing Autonomy and Paternalism in Private Law,* edited by A. Ogus and W. H. van Boom. Oxford: Hart Publishing, 2011.

Waddams 2011: Waddams, Stephen. *Principle and policy in contract law: competing or complementary concepts?*. Cambridge University Press, 2011.

Wade 1998: Wade, William. "The United Kingdom's Bill of Rights." In *Constitutional Reform in the United Kingdom: practice and principles*, edited by Beatson, Jack. Hart Publishing, 1998.

Wade 2000: Wade, William. "Horizons of horizontality" *LQR* 116, (2000): 220.

Wancata 2004: Wancata, Andrew. "No Value for a Pound of Flesh: Extending Marketinalienability of the Human Body." *JL & Health* 18 (2003): 199.

Weck 2005: Weck, Edward. "Exclusive Licensing of DNA Diagnostics: Is There a Negative Effect on Quantity and Quality of Healthcare Delivery That Compels NIH Rulemaking." *Wm. Mitchell L. Rev*. 31 (2004): 1057.

Wendler & Emanuel 2002: Wendler, Dave and Ezekiel Emanuel. "The debate over research on stored biological samples: what do sources think?." *Archives of internal medicin*e 162, no. 13 (2002): 1457-1462.

Wendler 2006: Wendler, David. "One-time general consent for research on biological samples." *BMJ* 332, no. 7540 (2006): 544-547.

Wicks, Ziegler and Hodson, 2015: Ziegler, Katja S., Wicks Elizabeth and Loveday Hodson (eds). *The UK and European Human Rights: A Strained Relationship?*. Bloomsbury Publishing, 2015.

Williamson 1979: Williamson, Oliver E. "Transaction-cost economics: the governance of contractual relations." *Journal of Law and Economics* 22, no. 2 (1979): 233-261.

Williamson 1998: Williamson, Oliver E. "The institutions of governance." *TAmerican Economic Review* 88, no. 2 (1998): 75-79.

Williamson 2002: Williamson, Oliver E. "The lens of contract: private ordering." *American Economic Review* 92, no. 2 (2002): 438-443.

Yann et. al 2005: Joly, Yann, Bartha M. Knoppers, and M. T. Nguyen. "Stored tissue samples: through the confidentiality maze." *Pharmacogenomics Journal* 5, no. 1 (2005): 2.

Young 2007: Young, Alison. "Horizontality and the Human Rights Act 1998." In *Human Rights and Private Law, Privacy as Autonomy,* edited by Katja Zigler. Hart Publishing, 2007.

Young 2014: Young, Alison. "Mapping Horizontal Effect". In *Constitutionalization of European Private Law*, edited by Hans-W. Micklitz. Oxford: Oxford University Press, 2014.

Young 2014(1): Young, Alison. "*The Human Rights Act 1998, Horizontality and the Constitutionalisation of Private Law*" in *Current problems in the protection of human rights: perspectives from Germany and the UK*, edited by Ziegler, Katja S., and Peter M. Huber. Bloomsbury Publishing, 2013.

Youngs 2016: H. Youngs, Raymond. "An uneasy Relationship: The influence of National and European Fundamental Rights in English Private Law." In *The Influence of Human Rights and Basic Rights in Private Law,* edited by Verica Trstenjak and Petra Weingerl, 559-576. Springer, 2016.

Zaccaroni 2019: Zaccaroni, Giovanni. "Egenberger, or the place of non discrimination on the ground of religion in the EU constitutional legal order." *Stato, Chiese e Pluralismo Confessionale*, 2019.

Zagrebelsky 1998: Zagrebelsky, Gustavo. *La giustizia costituzionale*. Bologna: Il mulino, 1988.

Zatti & Colussi 2003: Zatti Paolo and Colussi Vittorio. *Liniamenti di Diritto Privato.* CEDAM, 2003.

Zatti 2008: Zatti, Paolo. "Di là dal velo della personalità fisica. Realtà del corpo e diritti dell'uomo." In *Liber Amicorum per Francesco Busnelli. Il diritto civile tra principi e regole Volume II.* Giuffrè Editore, 2008.

Zeno-Zencovich 2019: Zeno-Zencovich, Vincenzo. *Comparative Legal Systems: A Short and Illustrated Introduction*." Roma: Roma Tre Press: 2019.

National, Supranational and International Law Documents

Anatomy Act 1984.

Autorizzazione n. 8/2016.

Autorizzazione n. 9/2014.

Codice Civile Italiano, R.D. 16 marzo 1942, n. 262**.** Gazzetta Ufficiale della Repubblica Italiana, n. 79, 4 Aprile 1942.

Codice Penale Italiano R. D. 19 October 1930, n. 1398. Gazzetta Ufficiale della Repubblica Italiana, n. 251, 26 Ottober 1930.

Costituzione della Repubblica Italiana. Gazzetta Ufficiale della Repubblica italiana n. 298, 27 Dicembre 1947.

Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine Oviedo*, 4.IV.1997**,** CETS 164

Council of Europe, *Convention for the Protection of Individuals with Regard to the Automatic Processing of Individual Data*, 28 January 1981, ETS 108

Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms*, as amended by Protocols Nos. 11 and 14, 4 November 1950, ETS 5

Council of Europe, *Explanatory Report to the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* ETS n. 164, paragraph 133

Council of Europe: Committee Of Ministers, *Recommendation* (*97)5* on the Protection of Medical Data, 1997

Council of Europe: Committee Of Ministers, *Recommendation Rec(2006)4 to Member States on Research on biological materials of human origin.*

Data Protection Act 1998

Data Protection Act 2018

Decreto legislativo 10 agosto 2018, n. 101.

Decreto legislativo 30 giugno 2003 n. 196.

Decreto legislativo 6 novembre 2007 n. 191.

European Union, Charter of Fundamental Rights of the European Union, 26 October 2012, 2012/C 326/02

European Union, Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC OJ L33/30.

European Union, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the

processing of personal data and on the free movement of such data. Official Journal No. L 281 of 23.11.1995.

European Union, Protocol (no 30) on the application of the Charter of Fundamental Rights of the European Union to Poland and the United Kingdom, OJ C-306/157, of 17th December 2007.

European Union, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC

Explanatory notes to the DPA 2018

Explanatory Notes to the Human Tissue Act 2004

Human Organs Transplants Act 1989.

Human Rights Act 1998,

Human Tissue Act 1961.

Human Tissue Act 2004

Human Tissue Authority, *Code of Practice A: Guiding Principles and the Fundamental Principle of Consent*, Human Tissue Authority 2017

Human Tissue Authority, *Code of Practice E: Reseach*, Human Tissue Authority 2017.

Legge 12 agosto 1993 n. 301.

Legge 16 dicembre 199 n. 483.

Legge 21 ottobre 2005 n. 219.

Legge 26 giugno 1967 n. 458.

Legge 28 marzo 2001 n. 145.

Legge 31 dicembre 1996 n. 675.

Legge 4 agosto 1955 n. 848.

Legge 6 marzo 2001 n. 52.

Loi n° 94-653 du 29 juillet 1994

Relazione del Ministro Guardasigilli Grandi al Codice Civile 1942. Testo e Relazione ministeriale. Biblioteca, Camera dei Diputati.

UN Educational, Scientific and Cultural Organisation (UNESCO), *International Declaration on Human Genetic Data*, 16 October 2003

UN Educational, Scientific and Cultural Organisation (UNESCO), *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997

UN General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, 217 A (III)

Guidelines and Reports

Corte Costituzionale, *I diritti fondamentali in Italia – Relazione italiana per la nostra Corte, presentata alla conferenza delle Corti costituzionali europee di Ankara* (7-10 maggio 1990), L'indice penale 1990.

Department of Health, *Reference guide for examination or treatment*, Second Edition, 2009.

Fondazione Smith Klein e Società Italiana di Genetica Umana*, Linee guida per I protocoli clinici di ricerca genetica*, 2006.

General Medical Council, *Guidelines on good practice in research and consent to research*, 2010.

Guidelines of the Medical Research Council, *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines*, 2014.

Guidelines of the Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues*, 1995.

Issac Report, HM Inspector of anatomy, the investigation of events that followed the death of Cyril Mark Isaac, May 2003.

National Bioethics Advisory Commission, *Research Involving human Biological Materials: ethical issues and policy guidance (Report and Recommendations),* 1995.

Report of a Census of Organs and Tissue in the Retained by Pathology Services in England, 2001.

The Bristol Royal Infirmary Inquiry Interim Report - Removal and retention of human material, 2000.

The Royal Liverpool Children's Inquiry Report, 2000.

Wellcome Trust Analysis, *Research and the General Data Protection Regulation*, 2016.

Case Law

CASE LAW

CJEU

Case C-26/62 *Van Gend & Loos v Nederlandse Administratie der Belastingen* [1963] ECR 1.
Case C-41/74 *Yvonne van Duyn v Home Office* [1974] ECR 133.
Case C-414/16 *Vera Egenberger v Evangelisches Werk für Diakonie und Entwicklung e.V.*, EU:C:2018:257.
Case C-43/75 *G. Defrenne v SABENA* [1976] ECR 455.
Case C-555/07 *Seda Kücükdeveci v Swedex GmbH & Co. KG*, EU:C:2010:21.
Case C-569/16 *Stadt Wuppertal v Maria Elisabeth Bauer and Volker Willmeroth v Martina Broßonn*, EU:C:2018:871.
Case C-68/17 *IR v JQ*. EU:C:2018:696.
Case C‑176/12 *Association de médiation sociale v Union locale des syndicats CGT and Others*, EU:C:2014:2.

ECtHR

28 April 20002, *Pretty v. United Kingdom*, (App. No. 2346/02).
25 April 1978, *Tyrer v. United Kingdom*, (App. No 5856/72).
27 Jun 1994, *C.R. v. United Kingdom*, (App. No. 20190/92).
22 November 1995, *SW v. United Kingdom*, (App. No. 20166/92).
4 December 1995, *Ribitisch v. Austria*, (App. No. 18896/91).
10 May 2001, *Cyprus v. Turkey* (App. No. 25781/94).
11 July 2002, *Goodwin v. United Kingdom*, (App. No. 28957/95).
9 March 2004, *Glass v. the United Kingdom* (App. No 61827/00).
24 June 2004, *Von Hannover v. Germany*, (App. No. 59320/00).
8 July 2004 *Vo v. France* (App. no. 53924/00).
10 April 2007, *Evans v. United Kingdom* (App. No. 6339/05).
16 December 2008*, Ada Rossi a.o. v. Italy* (App. Nos. 55185/08, 55483/08).
19 January 2010, *Bock v. Germany*, (App. No 22051/07).
28 August 2012, *Costa and Pavan v. Italy* (App. No. 54270/10).

UNITED KINGDOM

House of Lords, United Kingdom

Airedale NHS Trust v Bland [1993] A.C. 789.
Campbell v MGN Ltd [2004] UKHL 22.
Chester v Afshar [2004] UKHL 41.
Janson v Driefontain Consolidated Mines ltd [1902] A.C. 484.
McFarlane v Tayside Health, [1999] UKHL 50.
R. v Secretary of State for the Home Dept., exparte Limbuela [2005] UKHL 66.
Rees v Darlington memorial Hospital NHS Trust [2003] UKHL 52.
Richardson v. Mellish (1824) 2 Bing 229, 252.
S v McC; W v W [1972] AC 24.
Sidaway v Governors of Bethlem Royal Hospital [1985] AC 871.
Wainwright v Home Office [2003] UKHL 53.

Supreme Court, United Kingdom

Hounga v Allen & Anor [2014] UKSC 47.

High Court, England and Wales

AVB v TDD [2013] EWHC 1705 (QB).

Court of Appeal, England and Wales

Dobson v North Tyneside Health Authority and another [1997] 1WLR 596
Freeman v the Home Office (No 2) [1984] 1 QB 524.
Re A (conjoined twins) [2001] 2 WLR 480
Re T [1992] 4 ALL ER 649.

ITALY

Italian Supreme Court

Cass. Civ. 10 agosto 1953, no. 2696.
Cass. Civ. 10 aprile 1996, n. 3329.
Cass. Civ. 10 ottobre 2005, n. 20197.
Cass. Civ. 11 gennaio 1973, n. 63.
Cass. Civ. 12 novembre 1979, n. 5829.
Cass. Civ. 13 dicembre 2011, n. 26729.
Cass. Civ. 13 settembre 2005, no. 18128.
Cass. Civ. 14 febbraio 1984, n. 115.
Cass. Civ. 14 luglio 2002, n. 8503.

Cass. Civ. 14 settembre 2012, n. 15449.
Cass. Civ. 15 dicembre 1982, n. 6922
Cass. Civ. 15 giugno 1999, n. 5917.
Cass. Civ. 16 giugno 2011, n. 18641.
Cass. Civ. 17 luglio 1981, n. 4414.
Cass. Civ. 19 gennaio 2006, n. 1040.
Cass. Civ. 2 febbraio 2010, n. 2352.
Cass. Civ. 21 aprile 2010, n. 9441.
Cass. Civ. 23 maggio 1985, n. 2081.
Cass. Civ. 24 settembre 1999, n. 10511.
Cass. Civ. 25 ottobre 1997, n. 10505.
Cass. Civ. 26 maggio 2000, n. 6999.
Cass. Civ. 27 luglio 1987, n. 6492.
Cass. Civ. 27 maggio 1971, n. 1574.
Cass. Civ. 29 maggio 2014, n. 12061.
Cass. Civ. 29 settembre 2005, n. 19024.
Cass. Civ. 31 ottobre 2014, n. 23158.
Cass. Civ. 4 marzo 2003, n. 3185.
Cass. Civ. 5 luglio 1971, n. 2091.
Cass. Civ. 7 febbraio 1996, n. 978.
Cass. Civ. 7 marzo 2001, n. 3272.
Cass. Civ. 8 agosto 1997, n. 7344;
Cass. Civ. 8 luglio 1998, n. 6672.
Cass. Civ. 8 maggio 2006, n. 10490.
Cass. Pen. 16 giugno 1998, n. 9326.
Cass. Pen. 31 gennaio 1934 (Corte di Cassazione del Regno).
Cass. Pen. Sez. Un. 18 dicembre 2008, n. 337.
Cass. Sez. Un. Civili 11 gennaio 1973, n. 63.
Cass. Sez. Un. Civili 17 settembre 2015, n. 18214.

Italian Constitutional Court

Corte Cost. 1 aprile 1992, n. 149.
Corte Cost. 10 ottobre 1979, n. 125
Corte Cost. 11 aprile 2002, n. 135.
Corte Cost. 12 luglio 1979, n. 88.
Corte Cost. 14 luglio 1986, n. 184.
Corte Cost. 19 gennaio 1993, n. 10.
Corte Cost. 19 maggio 1997, n. 144.
Corte Cost. 2 giugno 1994, n. 218.
Corte Cost. 22 dicembre 1980, n. 188.
Corte Cost. 24 gennaio 1994, n. 13.
Corte Cost. 24 maggio 1963, n. 74.

Corte Cost. 24 maggio 1985, n. 161
Corte Cost. 24 novembre 1994, n. 419.
Corte Cost. 24 ottobre 2007, n. 348
Corte Cost. 3 febbraio 1994, n. 19.
Corte Cost. 3 luglio 1956 n. 11.
Corte Cost. 30 giugno 2003, n. 233.
Corte Cost. 4 maggio 1972, n. 77.
Corte Cost. 7 aprile 1988, n. 404.
Corte Cost. 7 marzo 2011, n. 80.
Corte Cost. 8 marzo 1962, n. 20.
Corte Cost. 8 marzo 2010, n. 93.
Corte Cost. 9 luglio 1996, n. 238.
Corte Cost. 9 ottobre 1990, n. 471.

Court of Appeal

Corte d'Appello di Roma, Sez. lavoro. Ordinanza 11 aprile 2002.

OTHER

Bundesverwaltungsgericht, Germany

(BVerwG) 15 December 1981, *Neue Juristische Wochenschrift* 1982.
(BVerwG) 30 January 1990, *Juristenzeitung*, 1990.

Conseil d'Etat, France

Assemblée, du 27 octobre 1995, 136727.

Courts of Appeals, United States

Washington University v. William J. Catalona, M.D. No. 06-2286. United States Court of Appeals for the Eight Circuit. June 20, 2007.
Schloendorff v. Society of New York Hospital (1914) 105 N.E. 92.

District Court, United States

Greenberg v. Miami Children's Hospital Research Institute. United States District Court, S.D. Florida, Miami Division. May 29, 2003. 264 F.Supp.2d 1064.

Rechtbank Noord-Holland, Netherlands

NL:RBNHO:2017:3955.